HEALTH

Healthy People. A Healthy Province.

Finding the Root Causes of Critical Incidents in Health Care

September 15, 2004

Saskatchewan Health

Version 3.1

NOTE: *The contents of this document are in draft format and are provided for information purposes only. For a response to any questions regarding this report, or to obtain an updated version of this document as it becomes available, please contact the Acute and Emergency Services Branch of Saskatchewan Health, attention Paula Beard and/or Jennifer White, Provincial Quality of Care Coordinators.*

The authors respectfully request that this work not be reproduced, in whole or in part, without their direct permission.

Table of Contents

Section 1. Preface ___ ***3***

Section 2. Introduction ___ ***5***

Section 3. Governance and Reporting ___ ***7***

3.1 Board of Directors ___ 7

3.2 Saskatchewan Legislative Framework for Healthcare Quality Improvement ___ 7

3.3 Basis for Reporting ___ 8

3.4 Roles and Responsibilities for the Investigation of Critical Incidents ___ 8

3.5 Reporting Critical Incidents to Saskatchewan Health ___ 9

Section 4. Root Cause Analysis ___ ***11***

4.1 Framework for Conducting a Root Cause Analysis ___ 12

Section 5. Adverse Events in Health Care ___ ***23***

5.1 Adverse Events in Canada ___ 23

5.2 Types of Adverse Events ___ 23

5.3 Concepts for Reducing Adverse Events ___ 26

Section 6. Preparing for the RCA ___ ***29***

6.1 Disclosure ___ 29

6.2 Notification ___ 30

6.3 Preparation for RCA ___ 30

6.4 Preparing for Discussion ___ 31

Section 7. Root Cause Analysis Day ___ ***33***

7.1 Participants ___ 33

7.2 Setting and Deportment ___ 33

7.3 Investigating Potential Root Causes ___ 34

7.4 Establishing Recommendations ___ 35

7.5 Implementing Recommendations ___ 36

Section 8. Conclusion ___ ***37***

Section 9. References ___ ***39***

Section 10. Appendices ___ ***41***

105-02195/

Section 1. Preface

"

The common initial reaction when an error occurs is to find and blame someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors. People working in health care are among the most educated and dedicated workforce in any industry. ***The problem is not bad people; the problem is that the system needs to be made safer.***

To Err is Human: Building a Safer Health System. Institute of Medicine, 1999

"

Traditionally, health care organizations have responded to critical incidents using what has become widely known as the "**Blame and Shame**" approach. When an incident occurs, the organization seeks to find the person responsible and follow up generally takes the form of disciplinary action. This approach is deeply flawed. Human beings are by their very nature incapable of perfect performance. Errors caused by the negligence or carelessness of health care professionals are rare. They do occur but, upon closer examination, adverse events are more frequently caused by one or more defects in the design of the system. Reducing or preventing the incidence of medical errors can only effectively be achieved through the identification and correction of defects in the system.

It is often the most experienced and dedicated professionals that are involved in critical incidents. When these individuals are singled out and blamed, other health care providers may stop providing information about adverse events to their organization. The discussion and evaluation of medical errors will be driven underground with the very real potential for the development of a culture of secrecy to exist in our healthcare organizations. This approach will only serve to jeopardize public safety and undermine confidence in our health care systems. "Urging clinicians to be more careful, cautious, or vigilant accomplishes little. Without changes to our approach, we will, like Alexander the Great, continue to slash through the knot instead of carefully untangling it" (Croskerry, 2003).

The "**Systems Approach**" to examining adverse health events acknowledges the basic premise that humans will make errors. Fatigue, distraction, and heavy workload all contribute to the potential for error (Veterans Affairs, 2004). When the individuals responsible for the health care system acknowledge that errors will occur, we will be in a position to reduce the potential for harm to our patients.

> *"The systems approach is not about changing the human condition but rather the conditions under which humans work."*
> *J.T. Reason, 2001*

The Institute of Medicine (Crossing the Quality Chasm, 2001) has identified four key underlying reasons for delivering health care of inadequate quality. Each factor plays an individual role, and each factor exacerbates the effect of the others.

1. The growing complexity of science and technology.
2. The increase in chronic conditions.
3. A poorly organized delivery system.
4. Constraints on exploiting the revolution in information technology.

Despite the inherent flaws in the system, however, our primary goal should be patient safety. Put simply, "*the health care environment should be safe for all patients, in all of its processes, all the time. This standard of safety implies that organizations should not have different, lower standards of care on nights and weekends or during times of organizational change*" (Institute of Medicine, 2001).

Root cause analysis (RCA) has great potential to improve patient safety in health care organizations. Striving to identify and address the root or underlying causes of all critical incidents will lead to a greater understanding of system errors and ultimately a safer health care system.

The "Finding the Root Causes of Critical Incidents in Health Care" document is intended to provide an introduction to the investigation and reporting of critical incidents. It is anticipated that organizations will use and modify this process as they continue to work towards developing a systems approach to improving patient safety.

Remember…nothing changes if you change nothing.

Section 2. Introduction

Infrequently, the provision of health care services by highly educated, well-intended healthcare providers results in unintended harm to patients (defined as an adverse health event). **A "critical incident" means a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority (RHA) or health care organization (HCO)"** (*Saskatchewan Critical Incident Reporting Guideline, 2004*). Critical incidents are the most serious type of adverse health events. When a critical incident occurs it is imperative that providers review the circumstances in an effort to understand the root causes of the adverse health event.

A "root cause" is the cause, that if it were corrected, would reduce the recurrence of similar incidents. Root causes are considered to be higher-order and fundamental causal factors that address the underlying system issues, rather than identify single problems or faults. A root cause can consist of a deficiency in a system, a management failure, inadequate competency, performance error, omission, non-adherence to procedure, or inadequate communication within an organization (Spath, 1999).

For the purposes of this document, the term "patient" is used to refer to any person or groups of persons accessing a health care service across all programs, either on an inpatient or outpatient basis.

Please note that the Canadian Patient Safety Dictionary has provided a recommended use for each of these, and other, terms (Davies et al., 2003) (see Appendix A).

Root cause analysis is:

- Inter-disciplinary, involving experts from the frontline services.
- Involving of those who are the most familiar with the situation.
- Continually digging deeper by asking why, why, why at each level of cause and effect.
- A process that identifies changes that need to be made to systems.
- A process that is as impartial as possible.

(Veterans Affairs NCPS, 2004)

The goal of an RCA is to find out:

1. What happened?
2. Why did it happen?
3. What can we do to reduce the likelihood of it happening again?

It is currently widely recommended that a **multidisciplinary team** of care providers conduct the RCA. Clearly those best positioned to review the adverse event are those with **direct involvement** in the incident. This approach presents a two-fold opportunity:

1. It brings the health care team together for a detailed examination of the events leading up to the incident. This may, and often does, lead to the discovery of information not previously known by all members of the care team.

2. It allows team members who may be profoundly impacted by the event to participate in improving the design of the system in which they will continue to work.

The idea of reviewing critical incidents for potential improvement strategies may seem like a **common sense** approach to quality improvement, however in a society with so many competing demands on health services and health care providers, it is often the case that the event is discussed briefly but rarely reviewed in detail. Health care providers involved in the event may be left feeling a great sense of grief and frustration about the outcome. Occasionally valuable and committed health care providers leave their profession. This is a scenario that we can ill afford.

RCA is an **invaluable tool** in that it permits the health care professionals involved in the incident an opportunity to also participate in the creation of solutions to reduce the likelihood of similar incidents recurring. This allows them to impact the system they work in and to take ownership over the changes implemented, rather than to feel that the changes are being forced upon them by senior management (Bagian et al., 2001).

There are events that would not be appropriate to review using a multidisciplinary root cause analysis forum. These include events thought to be the result of a criminal act, a purposefully unsafe act, an act related to substance abuse by provider/staff, or events involving suspected patient abuse of any kind. These issues should be referred to a suitable administrative process for resolution (Veterans Affairs, 2004).

The provision of healthcare services is set in one of the most **complex of environments** with even the simplest of procedures often requiring multiple steps and multiple provider input utilizing intricate and ever evolving technology. Root cause analysis was first used in engineering and in other similar service sectors including the aviation and aerospace industries (Rex et al., 2000). These industries have recognized the need to develop strategies to address high-risk activities. Those involved in the advancement of patient safety have learned to examine the lessons learned in these industries and have worked to adapt those lessons to the health care setting. Activities such as critical incident reporting and trending as well as failure mode effect analysis (FMEA) and RCA have all been adapted and implemented from other high-risk industries.

Section 3. Governance and Reporting

3.1 Board of Directors

As with any change, it is important to ensure that the Board of Directors is aware of the quality improvement activities undertaken in your organization. While support for RCA should exist throughout the organization, it is essential in Saskatchewan that the Board of Directors approve all committees designated for quality assurance purposes where privilege over proceedings is sought.

Enclosed for your review is a resolution that was passed in November of 2001 by the Saskatoon District Health Board. The wording is provided with the permission of the Saskatoon Health Region for information purposes only.

> *Whereas the Quality of Care Committee of the Medical Advisory Committee and the Medical Advisory Committee, and its subcommittees of each medical department and the subcommittees of each medical department's divisions, examine and evaluate, on an ongoing basis, the provision of care and service to patients, for the purposes of education of the medical and district staff and the improvement of the care, practices and services provided to patients,*
>
> *Be it resolved: that the board approve the above committee and subcommittees when conducting such examinations and evaluations, and reporting thereon, shall be and are hereby designated, effective from their inception onward, as a quality assurance committee as contemplated by Section 35.1 of the Saskatchewan Evidence Act and entitled to the protection thereof.*

3.2 Saskatchewan Legislative Framework for Healthcare Quality Improvement

Initially, quality improvement activities within hospitals were protected by *Section 35.1* of *The Saskatchewan Evidence Act* (see Appendix B). This section describes the extent to which quality assurance activities are protected. The Act makes clear that it is only opinion that is to be provided protection, thus allowing for a free exchange of ideas between professionals for the purpose of improving care provided to patients in Saskatchewan. Facts, including newly discovered facts not found in the health record, are discoverable. Organizations must disclose all facts in their possession or they risk losing the protection previously extended to the opinions. It is always advisable to seek a legal opinion when interpreting legislation.

Discussions with stakeholders revealed the need to **extend the privilege** provided to quality assurance committees in *Section 35.1* to Saskatchewan Health to facilitate the sharing of information and findings from critical incident reviews. It was subsequently determined, through consultation with partners that the solution would require a change to existing provincial legislation. *The Regional Health Services Amendment Act, 2004,* repealed and replaced *Section 58* of *The Regional Health Services Act, 2002* in order to provide protection for the **mandatory reporting of critical incidents** to Saskatchewan Health. The Amendment Act and accompanying regulations are included in Appendix C for your reference. The legislation came into force on September 15, 2004, and requires Regional Health Authorities and Health Care Organizations to notify, investigate, and report a defined list of critical incidents to Saskatchewan Health.

All provincial legislation is available from the Queen's Printer, Government of Saskatchewan, accessible online at www.qp.gov.sk.ca.

3.3 Basis for Reporting

An Institute of Medicine report (1999) identified the need for a systematic method of reporting adverse healthcare events. As a result of this recommendation, the National Quality Forum was asked to develop a list of core events that are considered to be both serious and preventable in nature. The outcome was the creation of a consensus report that identified **27 serious, reportable events**.

Upon review of these events, they were found to be largely facility-based and thus Saskatchewan Health chose to also include events that reflect our regional model of health care delivery, such as inter-regional patient transfers. The final product is the *Saskatchewan Critical Incident Reporting Guideline, 2004*, which identifies **40 critical incidents** that must be reported to Saskatchewan Health in accordance with the legislation (see Appendix D).

Reporting does not necessarily bring safety into the health care system (Hume, 1999). We need to determine the root causes of the events and implement change in the system where the incident occurred in order to improve patient safety.

3.4 Roles and Responsibilities for the Investigation of Critical Incidents

The **support** of the Chief of Staff and Medical Advisory Committee is essential if the review team is to include physician representation. In addition, the various disciplines that may participate in a review should be involved in the development of the organization's RCA policy. A sense of ownership and partnership will ensure success of the process.

There is the potential for a critical incident to become the subject of a **civil lawsuit**. The insurance company's legal counsel will be responsible for defending the organization

should a claim be made. It is therefore recommended that legal advice be sought surrounding the review process and applicable documentation.

Saskatchewan Health has developed a draft **critical incident review policy**. A copy of the draft policy as well as a critical incident flow chart and notification table are included in Appendix E. The policy was developed with the assistance of the Provincial Critical Incident Working Group (PCIWG) which was assembled in 1998 to assist in advising Saskatchewan Health on a number of issues related to critical incidents and patient safety in Saskatchewan. The working group consists of representatives of the College of Physicians and Surgeons of Saskatchewan, the Saskatchewan Registered Nurses' Association, the Saskatchewan Society of Physician Executives (formerly known as the Chiefs of Staff Association), select regional health authorities, and Saskatchewan Health.

Local jurisdictions are also encouraged to develop and approve a critical incident policy specific to their region. The Regina Health District Policy has been enclosed (Appendix F) as one potential model for regions to review and adapt. The policy is provided with the permission of the Regina Qu'Appelle Health Region for information purposes only.

3.5 Reporting Critical Incidents to Saskatchewan Health

A **systematic method** for capturing information about critical incidents is necessary to obtain details about the event and the systems in which the event occurred. This ensures that the organization is able to respond quickly to the event, that key information is retained, and that senior leaders have the opportunity to ensure that the record of the incident is complete and secured from a risk management perspective.

Individual organizations or regions should have risk management (defined in Appendix A) strategies in place for the identification and resolution of critical incidents. The method of identifying and reporting unusual incidents or occurrences should be widely known at all levels of the organization. Once completed, reports should be reviewed and categorized according to their severity.

It is the responsibility of all Saskatchewan Regional Health Authorities and Health Care Organizations to notify the Department **within three business days** of becoming aware of a critical incident meeting the criteria outlined in the Guideline. Following initial notification, they are required to investigate the incident and provide a report to Saskatchewan Health **within sixty days**. The report is to contain:

- The circumstances leading up to the incident;
- Any current practice, procedure or factor involved in the provision of the health service that contributed to the occurrence of the critical incident and, if corrected, may prevent a similar critical incident in the future;
- Actions taken, and actions intended to be taken, as a result of the investigation; and
- Any recommendations for improvements to the system.

It is the responsibility of Saskatchewan Health to **analyze and report** on the aggregate data. Most importantly, it is the responsibility of Saskatchewan Health to **share** among other Regional Health Authorities and Health Care Organizations any opportunities to improve the overall safety of the health care system that arise from the review of a specific critical incident. Without identifying and addressing the root cause(s), we risk repeating errors that have the potential to jeopardize the health of our public.

Saskatchewan Health has committed to broadly disseminate applicable system improvement opportunities in a deidentified manner. Following the review of a critical incident, any recommendation that may be applicable in other regions is shared in the form of an **Issue Alert**, which contains a general, deidentified description of the circumstances surrounding the incident and the recommendations that are provincially applicable (Appendix G). The Issue Alert does not include any identifying details of the incident, or the region in which the incident occurred. The Department also is responsible for **analyzing aggregate data and reporting** to our stakeholders on the types of incidents reported.

Section 4. Root Cause Analysis

Root cause(s) analysis is a systematic investigation technique that uses information gathered during a focused assessment of a critical incident to determine the underlying reasons for the deficiencies or failures. The goal is to prevent or reduce the likelihood of a recurrence by identifying these reasons and striving to eliminate or correct them through targeted quality improvement strategies. Root causes involve both process problems (localized) or problems within the entire system (systemic).

"Sustained improvements in services can only happen when root causes are correctly identified and resolved."

Patrice Spath, 1999

To be ***thorough*** an RCA must include:

- Determination of human and other factors.
- Determination of related processes and systems.
- Analysis of underlying cause and effect systems through a series of why questions.
- Identification of risks and their potential contributions.
- Determination of potential improvement in processes or systems.

(Veterans Affairs NCPS, 2004)

To be ***credible*** an RCA must:

- Include participation by the leadership of the organization and those most closely involved in the processes and systems.
- Be internally consistent.
- Include consideration of relevant literature.

(Veterans Affairs NCPS, 2004)

The RCA focuses primarily on systems and processes, not individual performance. The enclosed suggested framework for conducting an RCA will help organizations systematically review a critical incident.

4.1 Framework for Conducting a Root Cause Analysis

The following framework has been adapted from the Joint Commission on Accreditation of Healthcare Organizations. It is available online at www.jcaho.org.

JCAHO provides the following tool to aid in conducting an RCA. It includes the following summary questions which will assist organizations in the completion of the framework for conducting an RCA.

- Brief description of the event.
- Who participated in the analysis?
- When did the event occur?
- What area/service was impacted?
- What are the steps in the process, as designed? [a Flow Diagram(s)]
- What human factors were relevant to the event?
- How could equipment performance affect the outcome?
- What controllable factors directly affected the outcome?
- Were there uncontrollable external factors?
- What other areas or services are impacted?
- To what degree are staff properly qualified and currently competent for their responsibilities?
- How did actual staffing compare with ideal levels?
- What are the plans for dealing with contingencies that would reduce effective staffing levels?
- How has staff performance in the relevant processes been assessed? When was this last performed?
- How can orientation and in-service training be improved?
- To what degree is all information available when needed?
- To what degree is communication among participants adequate?
- To what degree was the physical environment appropriate for the processes being carried out?
- What emergency and failure mode responses have been planned and tested?
- To what degree is the culture conducive to risk identification and reduction?
- What are the barriers to communication of potential risk factors?
- To what degree is the prevention of adverse outcomes communicated as a high priority?
- What can be done to protect against the effects of uncontrollable factors?
- Was there a literature search done?

The following template and examples (referring to a variety of possible circumstances) are intended to provide a framework for regions conducting an RCA. Each analysis will reflect a unique combination of factors and the framework should be adapted to best meet the needs of the participants and organization.

Brief description of the event.
Briefly summarize the circumstances surrounding the occurrence including the patient outcome (e.g., death, loss of function).

Example: A thirty-six year old male admitted for left hernia repair on May 3, 2002. A right hernia incision was made when the surgeon realized the left side was to be performed. The right side was closed and the left hernia repair was completed.

Who participated in the analysis?
Please include a list, by position and title, of all team members who participated in the analysis.

Example: Orthopedic Surgeon, Preadmission Nurse, Surgical Nurse, OR Technician, Medical-Surgical Nurse, etc.

When did the event occur?
Include the date and time the event took place.

Example: May 3, 2002 at 1:30 pm.

What area/service was impacted?
Include all services impacted by the event.

Example: This might include Operating Room, Nursing, Medical Staff, Recovery Room, and Preadmission Testing.

What are the steps in the process, as designed? [a flow diagram(s)]
The organization may provide a Flow Diagram(s) of the steps in the process involving the occurrence. The organization may also list the key steps involved in the specific processes relating to the event. Ask yourself, are all issues in the flow addressed? Suggestions are outlined below.

- Flow-chart the process as designed.
- Flow-chart the process as it is usually done.
- Flow-chart the process as it was done when the critical incident occurred.
- Identify risk points and their contribution to the event.

Example: For wrong site surgery you may list specific steps within key processes such as Preadmission Assessment and Verification of Site, Site Verification and Assessment by Surgeon, Pre-anesthesia Assessment, Surgical Preparation and Verification of Site, etc.

What human factors were relevant to the event?
Evaluating the role of human performance factors that may have contributed to an event.

Example: Fatigue of staff involved, personal problems where staff were not focused on job tasks, complex critical thinking requiring knowledge based decisions, not following documented policy and procedure, stress, boredom or staff rushing to complete the task.

How could equipment performance affect the outcome?
List the various equipment utilized for that patient during the health care stay. To assist in evaluating these processes consider the following:

- Were bio-med checks done and up-to-date?
- Was the equipment where it was supposed to be? Why or why not?
- Were staff in-serviced on equipment? How long ago?
- How frequently is the equipment used?
- Were alarms, displays, and controls identifiable and/or operating properly?
- Is the equipment set-up and performing in accordance with the manufacturer's recommendations?
- Were there equipment recalls that were not addressed?
- Was equipment designed to accomplish its intended purpose?
- Were equipment parts defective?
- Was there a report to another agency regarding equipment defect (Health Canada, etc)?

Example: The PCA pump had not had the scheduled preventive maintenance check completed. The equipment was not functioning properly but the policy for marking defective equipment was not followed. The PCA pump was put into the wrong storage area, along with properly functioning equipment, without posting a sign indicating the equipment was broken. The equipment was then accessed for use on the patient.

What controllable factors directly affected the outcome?
Identify factors that may have contributed to the event that the organization has the ability to change by making process improvements.

Example: Site was marked and the prep scrub washed off the marking prior to site verification. Site verification did not occur with all involved, per organizational P&P (physician, nurse, anesthesiologist).

Were there uncontrollable external factors?
Uncontrollable external factors are those factors that the organization cannot change that contribute to a breakdown in internal processes. An organization should not be willing to assign many issues to this category. Although a factor may be beyond the organization's control, the organization may be able to minimize the factor's effect on patients.

Example: A hospital may not have control or be able to prevent circumstances that cause a power outage such as a lightning strike or flooding, but it can plan for these occurrences and be prepared to generate back-up emergency power. Or, a power outage may be due to a car hitting an electrical pole outside the hospital and the organization has placed warning signs with blinking lights, which are located before the pole.

What other areas or services are impacted?
List all other areas that have the potential for a similar event to occur. This will assist in implementing risk reduction strategies in other pertinent high-risk areas.

Example: A wrong site surgery occurred in the main Operating Room. An RCA was conducted and various opportunities for improvement were implemented. The Endoscopy area, Emergency room and any other area where a procedure is performed may be able to incorporate the recommendations for improvements to proactively prevent a similar occurrence.

To what degree are staff properly qualified and currently competent for their responsibilities?
Include all staff present, not just those who were determined to be involved with the event. Do not overlook physicians and allied health practitioners. Ask the following questions:

- Determine if staff were formally trained to perform the specific duties or tasks involved in the event.
- Was the training adequate?
- Were staff qualified to use the equipment?
- Were competencies documented?
- Had procedures and equipment been reviewed to ensure a good match between people and tasks performed?
- Was there agency staff who may not have been familiar with procedures/equipment?
- Was float staff from another area assisting without receiving orientation to the unit they floated to?
- Was the individual new and performing a function that they were not oriented/trained/competent in performing?
- Were staff oriented to the organization and department specific policies/procedures?

Example: Surgical team members identified that they had received appropriate orientation to the equipment however no specific training on handling malfunctions.

How did actual staffing compare with ideal levels?
Was there appropriate staffing at the time of the event to address the required workload? Keep in mind if it was a weekend, change of shift, holiday, break time. Document the actual staffing in the area of occurrence versus planned staffing according to the staffing model. Explain any variation; higher or lower staffing.

Example: The staffing model was reviewed. Actual staffing exceeded the required numbers. However, two of the four RNs were participating in a staff meeting at the time of the event.

What are the plans for dealing with contingencies that would reduce effective staffing levels?
Summarize current plans in place to deal with staffing deficiencies.

Example: Plans are in place to use casual nurses, contact part time staff for extra hours, utilize critical care nurses for overtime. Surgery cancelled all elective procedures and all other procedures are prioritized according to protocol. Beds are closed when there is not enough staff.

How has staff performance in the relevant processes been assessed? When was this last performed?
Consider staff performance relative to the specific processes associated with the event.

Example: A casual nurse was assigned to the patient and had not completed her orientation to the department policy and procedure for marking the correct body site prior to surgery. A new physician was assigned to the ER and had not been oriented to the medical staff manual (MS Bylaws - R&Rs).

How can orientation and in-service training be improved?
Were all staff oriented to the job responsibilities, organization, and policies and procedures regarding safety, security, hazardous materials, emergency, equipment, life-safety, treatments, and procedures? Are policies revised/updated, evidence based, and readily available? Have policies or procedures changed without providing additional training? Was a new policy developed and staff training conducted? Do float staff receive training within the areas they are assigned? Is this documented?

Example: A policy change regarding the requirements for use of the new IVAC pump had been implemented approximately six months prior to the event. A formal in-service training program had not been completed. The policy was posted for all staff to read and sign off.

One staff member had not read the policy changes. The company representative left a business card for formal demonstration of the use of equipment but a date had not been secured to provide the demonstration. The skills checklist had not been revised to incorporate the use of this piece of equipment.

To what degree is all information available when needed?
Was information from various patient assessments completed, shared, and accessed by members of the treatment team as required by policy? Was the patient correctly identified? Was the documentation clear and did it provide an adequate summary of the patient's condition, treatment, and response to treatment? Was the level of automation appropriate? Identify what information systems were utilized during patient care.

Examples: No instruction for use of neonatal ambu bag available on code cart or med room.
No policy and procedure for pump settings.
Transfer form reported at risk for falls. Notification missing on chart.
No allergies noted on chart.

To what degree is communication among participants adequate?
Look at this content to cover verbal and lack of verbal/written communication(s).

- Physician to….
- Nurse to….
- Tech to….
- Pharmacist to….
- Hierarchical issues….
- Cultural issues….

And any other combination you can find during your investigation.

Example: Respiratory Therapist did not communicate unfamiliarity with the equipment to supervisor prior to patient care. Why? Drill down.

- Was communication of key information completed in a timely manner?
- Was there a misunderstanding of information shared based on a language barrier, abbreviations, terminology, etc.?
- Was shift-to-shift or unit-to-unit communication completed properly?
- Were there adequate policies and procedures in place to describe what is required?
- Is patient/family/significant other involved when needed in communication of information?
- Was adequate information communicated when a patient transferred from one area to another and was this communication of essential information documented? (Hemodynamics, orders, medications, labs, etc.)

To what degree was the physical environment appropriate for the processes being carried out?
Look closely at the environment the patient was in or was transferred to/from. Spaces, privacy, safety, and ease of access are a few items to consider. Was work performed under adverse conditions (hot, humid, improper lighting, cramped, noise, construction projects)? Had there been environmental risk assessments conducted? Did the work environment meet current codes, specifications, and regulations? Was the work environment appropriate to support the function it was being used for?

Example: Eight surgical suites have the head of the table facing north and the 9th suite has the head of the bed facing south. Would redesign reduce the risk of wrong side surgery? If a patient committed suicide by hanging a sheet from the top of the bathroom door, do you remove several inches off the door? Drill down how did the patient obtain the sheet? Did patients have open access to the sheets?

What emergency and failure mode responses have been planned and tested?
Had appropriate safety evaluations and disaster drills been conducted? Had provisions been planned and available to support a breakdown in operations?

Example: Emergency generators are routinely tested monthly with a full load. The generators had performed without problem at the most recent check, approximately three weeks prior to the failure. At that point, generator # 2 had recorded just 554 hours of use, in an estimated life of 44,000 hours. It was later identified that firing up the generators for their monthly checks ages them more rapidly than regular use.

To what degree is the culture conducive to risk identification and reduction?
Did the overall culture of the facility encourage or welcome change, suggestions, and warnings from staff regarding risky situations or problematic areas? Does management establish methods to identify areas of risk or receive employee suggestions for change? Are changes implemented in a timely manner?

Example: Members of the management team participate in meetings related to serious adverse events. A confidential suggestion box and hotline have been established to report high-risk issues and each of these are read and evaluated by the management team. Actions are taken on a regular basis.

What are the barriers to communication of potential risk factors?
Has the organization identified barriers to effective communication among caregivers? If there are no barriers, what have you done and how do you know it has been successful? Be specific.

Example: Nurse may have fear of retribution regarding the deterioration of their relationship with medical staff if the chain of communication policy was implemented and they follow the next level in command.

To what degree is the prevention of adverse outcomes communicated as a high priority?
Explain leadership's role and how it is put into practice. Provide examples.

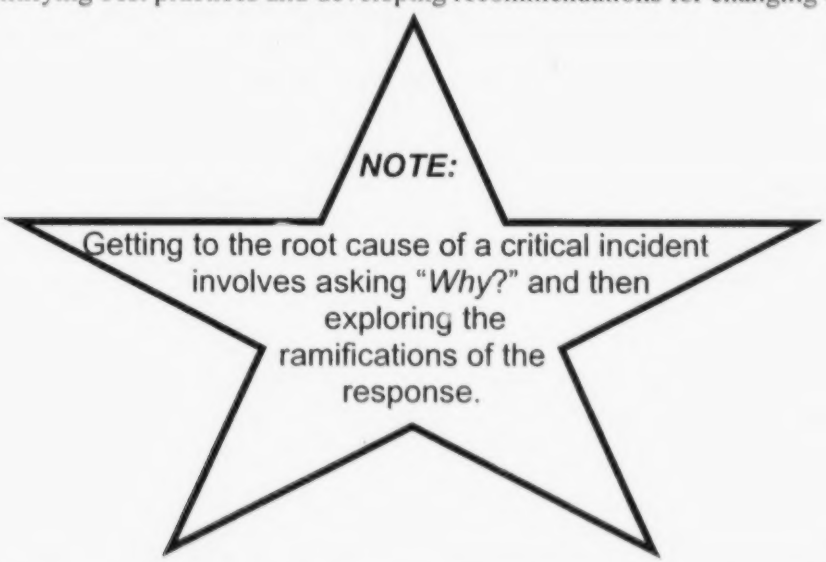
Example: Timely response to an adverse outcome is one of the organization's strategic goals. "Disclosure of Unanticipated Outcomes Policy" has been written and the responsible parties inform the patient/family about these outcomes of care.

What can be done to protect against the effects of uncontrollable factors?
When looking at uncontrollable factors, review the system the patient went through.

Example: Power failure from thunderstorm.
EMTs arrive at the wrong door.
Patient denies substance abuse.
Physician had a flat tire.

After listing examples, drill down further on each one and determine what action could be put in place to prevent the event or offer an alternative for action.

Was there a literature search done?
List all sources of literature accessed to complete the analysis and action plan. Literature may be accessed to assist in analyzing the event to determine process breakdowns and/or when developing actions once the root causes have been identified. It may also assist in identifying best practices and developing recommendations for changing current practice.


NOTE:
Getting to the root cause of a critical incident involves asking "*Why*?" and then exploring the ramifications of the response.

JCAHO Action Plan Suggestions

A detailed risk reduction strategy should be stated for each root cause identified. If a risk reduction is not warranted for the identified cause, an explanation is required. A risk reduction plan may also be developed for all other areas identified through the analysis as opportunities for improvement but that may not be considered root causes. The following template may be used.

Root Cause(s) / Opportunity for Improvement(s)	Risk Reduction Strategy	Person(s) Responsible for Implementation	Date of Implement-ation	Measurement Strategy
Communication Among Staff Members SAMPLE ONLY	Revise site verification policy and procedure to include immediate time out verification of site prior to procedure with both attending surgeon and staff participation.	Manager of Operating Room	Sept 2002	OR Manager or designee will directly observe cases to determine compliance with physician and OR staff completing time out verification of site prior to procedure in accordance with policy revisions. 100% compliance in all observed cases is expected.
	Identify all policies and procedures requiring changes and make revisions.	Manager of Operating Room and Chair for Nursing Policy and Procedure Committee.	Sept/Oct 2002	
	Present revised policies and procedures for approval to Nursing Policy and Procedure Committee and Department of Surgery Medical Staff Committee	OR Manager/ Chair of Dept. of Surgery	Nov 2002	
	Educate staff through OR staff and Medical Staff in-services and communication in Medical Staff bulletin	OR Manager/ Chairperson of Dept. of Surgery	Nov/Dec 2002	
	Incorporate education process into both new employee/physician and agency orientation	OR Manager/ Chair of Dept. of Surgery	Nov/Dec 2002	
	Complete data collection monitoring process for minimally six months.	OR Manager	Jan-June 2002	

Root Cause(s)/Opportunity for Improvement(s):
Highlight and summarize the root cause(s)/ Opportunity for Improvement(s) Issue identified during the RCA.

Risk Reduction Strategy:
Outline in detail the action plan steps taken to promote change. Be specific. If you change a policy and procedure, summarize the change that you are making. Outline how you are going to implement the policy and procedure (e.g., educate staff, perform post test for staff, etc.).

Person(s) Responsible for Implementation:
Identify by title the individual responsible for implementing the particular risk reduction step.

Date of implementation:
Outline the anticipated date of completion of each identified step. Outline the actual completion date for steps already completed.

Measurement Strategies/Measures of Effectiveness:
Outline the plan for measuring the effectiveness of each risk reduction strategy.
Indicators must be objective, measurable, and quantifiable. Use outcome based measurements whenever possible.
Measures of effectiveness need to have the data collection methodology outlined.
Using a random sample? Define random. Give sample size and method of collecting.
Are you determining effectiveness by observation? Pre-test/post-test? Pilot test? Audit tool? Explain.
Set a target range that reflects the desired range of performance for each indicator

Examples of Measurement Strategies:

- Following a policy and procedure change, all nursing staff will demonstrate competency.
- 15 patients per day entering the ER, 3 per shift will be evaluated from time entering facility until time to treatment to determine average ER waiting times. All expected waiting times should be within ("X") minutes for emergent patients and less than ("X") hours for non-emergent patients.
- Falls per 1000 patient days will be less than ("X") per month
- Patient Satisfaction with pain management will be evidenced by level of ("X") or above on Likert scale.

External comparisons may be used to develop indicator data and target measures.
Sources for external comparison data are performance measurement systems, professional organizations or societies, and research articles.

Section 5. Adverse Events in Health Care

5.1 Adverse Events in Canada

In May of 2004, the Canadian Medical Association Journal published The Canadian Adverse Events Study, lead by Dr. Ross Baker and Dr. Peter Norton (Baker et al., 2004). The study, based on the retrospective chart review of 3,745 charts across five Canadian provinces, revealed an adverse event rate of approximately 7.5% in Canadian hospitals. The investigators judged 36.9% of the adverse events to have been preventable.

A high proportion of adverse events (64.4%) resulted in no injury to patients. Unfortunately, 5.2% of all adverse events resulted in permanent disability and 1.6% of adverse events were associated with patients who subsequently died. In speaking about the adverse events study and the considerable interest that it has generated in the Canadian general public and international media, Dr. Baker cited the following seven conditions as precursors to errors:

* Reliance on ***memory***
* Reliance on ***vigilance***
* ***Non-standard*** processes
* Excess number of ***handoffs***
* Variable ***information*** available
* Excessive ***workload***
* Inconsistent ***feedback***

5.2 Types of Adverse Events

The U.S. Veterans Affairs National Center for Patient Safety (2004) has outlined six major categories of adverse events. Three categories are based on human error, originating with communication, training, or fatigue and scheduling. The remaining categories are based on adverse events as a result of equipment or the surrounding environment, adverse events originating with rules, policies, or procedures, or adverse events that arise due to barriers. Questions that may help to assess the type of error that occurred are included below.

1. **Human Factors - Communication:**
   Questions that help assess issues related to communication, flow of information, and availability of information as needed. These questions also reveal the

importance of communication in use of equipment and application of policy and procedure, unintended barriers to communication, and the organization's culture with regard to sharing information.

For example: A patient has his identifying bracelet removed during a procedure, and it is not replaced. The patient is later administered medication based on the nurse's memory of the patient's identity. The hospital has a policy requiring that wrist bracelets be checked before every dose of medicine, but because the dose is overdue, the nurse delivers the medicine without confirming the patient's identity.

2. **Human Factors - Training:**
   Questions that help assess issues related to routine job training, special training, and continuing education, including the timing of that training. Training issues may concern application of approved procedures, correct use of equipment, or appropriate manipulation of protective barriers. These questions also focus attention on the interfaces between people, workspace, and equipment.

   For example: A new group of physicians in residency training arrived this week to start a rotation at your facility. A lab critical incident occurs when the wrong form is submitted with a blood vial.

3. **Human Factors - Fatigue/Scheduling:**
   Questions that weigh the influence of stress and fatigue that may result from change, scheduling and staffing issues, sleep deprivation, or environmental distractions such as noise. These questions also evaluate relationships to training issues, equipment use, management concern and involvement.

   For example: Renovation is taking place in adjoining space making it difficult for staff to converse and to hear patient call alarms.

4. **Environment/Equipment:**
   Questions to help evaluate factors related to use and location of equipment; fire protection and disaster drills; codes, specifications and regulations; the general suitability of the environment; and the possibility of recovery after a critical incident has occurred. These questions show that what appears to be equipment failure may relate to human factors issues, policy and procedure questions and training needs.

   For example: Housekeeping staff are thorough in their care of bedding material. While the patient is in physical therapy they flip a patient's air-filled anti-decubitis mattress inadvertently reversing the correct alignment of the air chambers.

5. **Rules/Policies/Procedures:**

   Questions that help assess the existence and ready accessibility of directives including technical information for assessing risk, mechanisms for feedback on key processes, effective interventions developed after previous events, compliance with national policies, the usefulness of and incentives for compliance with codes, standards, and regulations. The qualifications of the facility and employees for the level of care provided; orientation and training for compliance with safety and security measures including handling of hazardous material and emergency preparedness; and the availability of information to all part time, temporary, or voluntary workers and students are also considered.

   For example: A nurse hired for the day through the local registry is not familiar with your facility's policy against unlocking the door to the balcony in order to smoke while taking a break.

6. **Barriers:**

   Barriers protect people and property from adverse events. Questions assess barrier strength, fault tolerance, function and interaction/relationship to Rules/Policies/ Procedures and Environment/Equipment.

   For example: A negative pressure room for an infectious patient is a barrier to the spread of the disease. If the ventilation in the room stops working a critical barrier has been compromised.

Veterans Affairs (2004) has also created five rules of causation, which were designed to improve the RCA process by creating minimum standards for where an investigation and the results should be documented.

Rule 1 – Causal Statements must clearly show the "cause and effect" relationship.
When describing why an event has occurred, you should show the link between your root cause and the bad outcome, and each link should be clear to the RCA team and others. Focus on showing the link from your root cause to the undesirable patient outcome you are investigating. Even a statement like "resident was fatigued" is deficient without your description of how and why this led to a slip or mistake. The bottom line: the reader needs to understand your logic in linking your causes to the outcome.

Rule 2 – Negative descriptors (e.g., poorly, inadequate) are not used in causal statements.
As humans, we try to make each job we have as easy as possible. Unfortunately, this human tendency works its way into the documentation process. We may shorten our findings by saying "maintenance manual was poorly written" when we really have a much more detailed explanation in our mind. To force clear cause and effect descriptions (and avoid inflammatory statements), we recommend against the use of any negative descriptor that is merely the placeholder for a more accurate, clear description. For example, words like "carelessness" and "complacency" do little to describe the actual conditions or behaviors that led to the mishap.

Rule 3 – Each human error must have a preceding cause.
Most of our mishaps involve at least one human error. Unfortunately, the discovery that a human has erred does little to aid the prevention process. You must investigate to determine WHY the human error occurred. It can be a system-induced event (e.g., step not included in medical procedure) or an at-risk behavior (doing task by memory, instead of using a checklist). For every human error in your causal chain, you must have a corresponding cause. It is the cause of the event, and not the human error itself, which leads us to productive prevention strategies.

Rule 4 – Each procedural deviation must have a preceding cause.
Procedural violations are like adverse events in that they are not directly manageable. Instead, it is the cause of the procedural violation that we can manage. If a clinician is violating a procedure because it is the local norm, we will have to address the incentives that created the norm. If a technician is missing steps in a procedure because he is not aware of the formal checklist, work on education.

Rule 5 – Failure to act is only causal when there was a pre-existing duty to act.
We can all find ways in which our investigated mishap would not have occurred - but this is not the purpose of causal investigation. Instead, we need to find out why this mishap occurred in our system as it is designed today. A doctor failing to prescribe a medication can only be causal if he were required to prescribe the medication in the first place. The duty to perform may arise from standards and guidelines for practice, or other duties to provide patient care.

5.3 Concepts for Reducing Adverse Events

Dr. Donald Berwick (1996) outlined the following ten ways to reduce adverse events in medical care:

1. **Simplify.** Reduce the number of steps and hand-offs in work processes. Reduce nonessential elements of equipment, software, and rules of procedure.

2. **Standardize.** Limit unneeded variety in drugs, equipment, supplies, rules, and processes of work.

3. **Stratify.** Identify strata of need, and "mass-customize" to each stratum. Avoid "one size fits alls." Substitute "5 sizes fit 80%."

4. **Improve auditory communication patterns.** Use repetition, standard vocabularies, and unmitigated communication.

5. **Support communication against the authority gradient.** Use lessons from "cockpit resource management" (crew resource management). Train for team communication. Huddle. Use nominal group methods and other group processes that increase exchange.

6. **Use defaults properly.** Design processes so that the safe channel is the one requiring the lowest energy. Make "doing the right thing" the easiest thing to do.

7. **Automate cautiously.** Avoid over-automating systems and equipment. Make sure that operators can know the true state of the system, can override automation effectively, and can maintain proper vigilance. Make the system visible to the user.

8. **Use affordances and natural mapping.** Let the environment and equipment "speak", informing the user about proper use. Use visual controls. Minimize translation steps between instructions and their effects. Design physical shapes and flows to guide proper use. Increase "knowledge in the world" so as to reduce reliance on "knowledge in the head."

9. **Respect limits on vigilance and attention.** When designing tasks and worksystems, keep in mind issues of stress, workload, circadian rhythm, time pressure, limits to memory, and properties of human vigilance. Design for normal human behavior and capacity.

10. **Encourage reporting of errors and hazardous conditions.** Assume the requirement of anonymity until otherwise proven. Reward reports. Build a culture that celebrates the increase of knowledge on the basis of which error rates can be reduced and risks mitigated.

Section 6. Preparing for the RCA

When a critical incident occurs, pressure to act can mount quickly. Organizations will be best positioned to deal with the incident if there is a clear sequence of events to be initiated whenever a critical incident occurs. Typically, preparation for the RCA should consist of the following pieces: disclosure/notification, interviews, chart reviews, collection of relevant policies and procedures, and a literature review.

6.1 Disclosure

The disclosure to the patient or their designate should occur **as soon as reasonably possible** after the event, and in keeping with local policy. The patient will provide further insight into the adverse event and the system in which it occurred. Including details of the patient's experience in the RCA offers yet another valuable perspective from which the system can be examined.

When conducting a family meeting it is advisable to provide as many known facts as possible. It is not advantageous, especially in the early stages of fact gathering, to speculate about the cause of the event. Ideally, **all known facts should be provided** in addition to a discussion of how the organization will undertake to review the incident.

While it is not within the scope of this manual to provide detailed discussions of disclosure of harm to patients, it is valuable to identify this as a broader component of resolving critical incidents. Patients or their substitute decision-makers should be notified of critical incidents related to the provision of health care services. Saskatchewan Health has developed a draft guideline outlining common elements to be included in regional disclosure policies (see Appendix H). The College of Physicians and Surgeons of Saskatchewan has counseled their members to disclose adverse events; the Canadian Medical Protective Association has also counseled their members to disclose events to their patients. The province of Quebec is the first province in Canada to legislate disclosure of adverse health events.

Patients or their designate may request a **follow-up meeting** after the initial disclosure meeting occurs. Frequently family members are seeking to ensure that the critical incident has been thoroughly reviewed and change has been implemented so that other patients won't have similar experiences. The level of detail provided to the patient as to specific recommendations made during the review can vary by case. It is clear that opinions expressed during an RCA must not be released. In certain circumstances, the specific recommendations that arise from the RCA may be released to the patient or family following implementation. If there is any uncertainty as to whether to release recommendations, the advice of legal counsel should be sought.

6.2 Notification

A number of stakeholders will require notification of the event (please see the notification table in Appendix E). Depending on how the incident was identified, various care providers and levels of the organization's administration will need to be made aware of the incident. The attending physician should be notified as soon as possible (if not already aware). Other internal notifications may include the CEO, risk management, medical managers, health records staff, and unit or program managers. If the event has been made public, communications department personnel may also need to be notified. External notifications may include those mandated through legislation, such as the Coroner, Health Canada, other regulatory agencies, and insurers. In response to the incident, insurers may wish to initiate a claim on behalf of the organization and have legal counsel undertake to interview witnesses and secure evidence related to the event.

It is valuable to **have a contact list prepared in advance** so that both internal and external partners can be readily notified about the incident, and provided with the information they require to make decisions and take action.

6.3 Preparation for RCA

Interviews
In addition to speaking with the patient or designate, fact gathering should also include interviews with staff, chart reviews, and a review of applicable policies and procedures. It is beneficial to interview staff involved in the critical incident **as soon as possible** in an effort to record the sharpest version of the events. Memory can fade, and as time elapses recollections can be affected by discussions surrounding the event. A timely interview will increase the probability of obtaining the most accurate sequence of events.

Wherever possible, interviews should be conducted by the facilitator to assist in **establishing a trusting relationship**.

Ideally, care team members should be asked to refrain from discussing the incident with one another outside of quality assurance processes. This is a difficult thing to ask the staff to do – involvement in a critical incident can be traumatic for the health care providers involved, and talking about it is a natural coping mechanism. There are appropriate forums for this to happen. These may include involving your organization's critical incident stress management (CISM) team, which may include peers, counselors, social workers, etc. It is important to emphasize that the fact gathering interview should occur in advance of invoking the services of the CISM team.

Chart Review
Health records staff should **secure the original health record** and control access to it immediately following notification. If it is necessary to continue to have the health record available to care providers, then a copy should be sent to the ward or unit.

The RCA facilitators should review the chart for the purpose of determining the sequence of events leading up to and immediately following the critical incident. During this

review, it is possible that inconsistencies and gaps in charting may be identified. This should be noted in discussions with insurers or legal counsel. Attempts to clarify and record subsequent information obtained through other sources should be identified as such and included in the chart review.

Policies and Procedures
There will be regional and/or provincial policies and procedures that are relevant to the critical incident and these documents should be reviewed prior to and available during the RCA. These policies and procedures will prove useful in **establishing the standard of care** to which the organization and their individual care providers will be held. They are also frequently the subjects of change following a review.

6.4 Preparing for Discussion

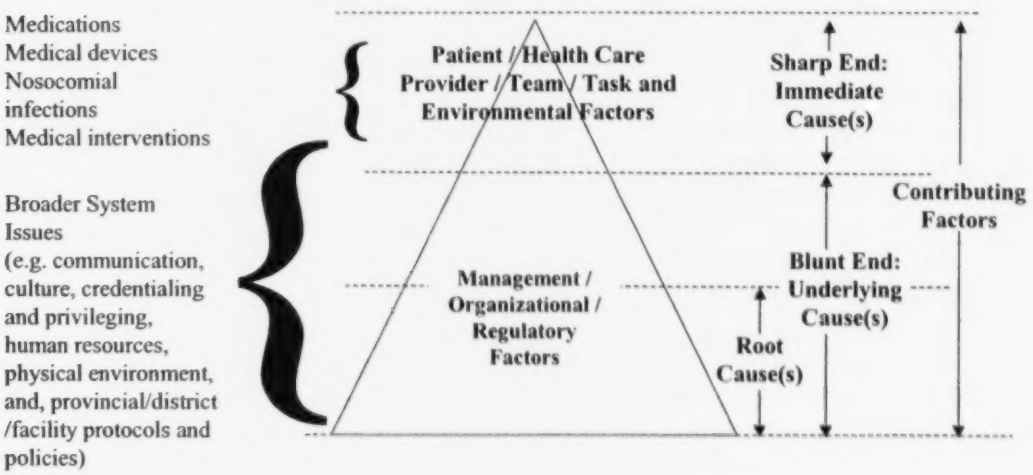
In anticipation of an RCA, a **sequence of events** should be developed merging facts from as many sources as possible. The sequence should be marked draft and reviewed by the multidisciplinary review team so that a common set of facts can be agreed to prior to examining them for potential root causes.

An experienced facilitator will be able to anticipate the issues that are likely to arise during discussions. By preparing information in advance (e.g. conducting reviews of the relevant literature), the team will be better informed and able to identify best practices and evidence-based solutions.

The Joint Commission on the Accreditation of Healthcare Organizations has developed a **root cause analysis matrix** (Appendix I). Use of the matrix will initially assist the facilitator in initially identifying some potential causes, based on the type of event.

Facilitators must be mindful of the system in which they are trying to effect change. Frequently, the system is separated into two distinct components: the **sharp end** and the **blunt end**. The sharp end of the system represents the point of delivery of health care services to the client. The blunt end of the system represents the more broad health care organizational system, including policies and procedures, IT systems, staffing patterns, and the physical structure of the place of care (see Figure 1 below) (Wilder, 2003).

Figure 1. The Sharp and Blunt Ends of the Health Care Delivery System.
(adapted from Woods 1994).


Medications
Medical devices
Nosocomial infections
Medical interventions
Broader System Issues (e.g. communication, culture, credentialing and privileging, human resources, physical environment, and, provincial/district /facility protocols and policies)
Patient / Health Care Provider / Team / Task and Environmental Factors
Sharp End: Immediate Cause(s)
Contributing Factors
Management / Organizational / Regulatory Factors
Blunt End: Underlying Cause(s)
Root Cause(s)

Section 7. Root Cause Analysis Day

Conducting an RCA will require a commitment of two to three hours for discussions. Despite all reassurances provided to participants, it can still generate a great deal of anxiety among staff. In an attempt to offset this discomfort, participants should be provided with the organizational policy pertaining to the RCA process in advance of the review day (see Appendix F for an example from the Regina Health District). As well, participants should be invited to freely discuss the **review process** with the facilitator or peers with previous RCA experience if they so wish.

7.1 Participants

The participation of the attending physician, consulting specialist(s), and all staff members who provided care during the critical incident will be **pivotal to the success** of the review. As indicated in Section 2 (Introduction), these individuals experienced the event first hand and likely have given significant consideration to how the critical incident might have been prevented. These team members frequently have meaningful experience with the system in which they work and are best positioned to provide solutions.

On occasion, staff may request that union representation or legal counsel attend the meeting. While the process works best with a small group of personnel who have intimate knowledge of the event, these representatives may be invited if necessary. It is important they understand that they are bound by the same confidentiality requirements as all others in attendance.

It is also necessary to include appropriate senior administrative staff in the review. These individuals have primary responsibility for much of the system in which the provision of services occurs. Their participation can demonstrate a **commitment to change** at the highest levels of the organization. Additionally, they are often given the responsibility to oversee the development and implementation of recommendations for system change.

Occasionally, it may also be appropriate to involve relevant consultants with specialized knowledge of the system undergoing review.

7.2 Setting and Deportment

Ideally, the review should take place in a **comfortable, private room** with adequate space for participants. Since the review requires an extensive time commitment, it is advisable to provide refreshments for participants. A boardroom or a U-shaped table setting will best facilitate discussions among the review team.

Documentation provided to the team during the RCA should be tracked and required to be returned to the facilitator at the end of the review meeting.

The facilitator will set the tone for the meeting by providing clear guidance on the team's mandate at the outset. It is also prudent to reiterate that the review will address issues related to the system in which the event occurred and will **not** address issues related to individual competencies. Occasionally the review team will venture into blaming statements. If this occurs, it is essential for the facilitator to change the focus of the conversation to overall education and training needs as possible contributing root causes, and not allow individual performance to be singled out.

"We don't believe people come to work to do a bad job or make an error, but given the right set of circumstances any of us can make a mistake. We must force ourselves to look past the easy answer that it was someone's fault - to answer the tougher question as to why the error occurred. It is seldom a single reason." *Veterans Affairs NCPS, 2004*

Periodically, care providers will bring pre-existing issues into the review. It will be advantageous for the facilitator to understand the dynamics related to these issues so that appropriate methods of addressing these concerns can be developed in advance of the review. These dynamics will generally come to light during the interview process prior to the RCA.

7.3 Investigating Potential Root Causes

Once the ground rules have been clearly established and introductions completed, the next step is to present a draft **sequence of events**. Participants should be encouraged to provide additional facts or correct inaccuracies during this phase of discussions. It is the sequence of events that will provide the foundation for the remainder of the review, and all efforts should be made to try to achieve consensus.

When the team has **achieved consensus** on the sequence of events surrounding the critical incident, the review can begin to focus on system issues that may have contributed to the critical incident. Everyone present should be encouraged to participate in the discussions. It will be the responsibility of the facilitator to ensure that participants stay on point. If the review team strays too far from the issue at hand, they risk exceeding their mandate.

There are a number of techniques available to the facilitator that will assist in illustrating the care processes involved with the critical incident. Development of cause and effect diagrams, tree diagrams, Pareto diagrams, and flow-charting can all be useful tools in this regard. **By seeing the care processes illustrated, the team can begin to identify where issues arose and subsequently identify possible root causes.**

One particularly effective method of illustrating care processes is the use of Ishikawa diagrams (fishbone) and care maps. An Ishikawa diagram can be utilized to identify

possible root causes according to category. Once the categories have been identified, a care map can be developed for each category showing each step in a given process. In the health care field, a seemingly simple task such as the administration of medication has multiple interacting steps and feedback loops. Developing a care map allows the review team to focus on the specific steps in the process that were or could have been problematic (see Appendix J and K).

Discussions should focus on areas that can be improved. Issues related to financial and human resources may be easily identifiable, but are not easily solved. Facilitators should be encouraged to **delve deeper** to identify specific roots of the problem that will be of greater consequence. For example, instead of focusing simply on the number of staff available at the time of the incident, discussions should reflect upon training/continuing education requirements, staffing patterns, supervision, and patient demands on staff members.

When all of the potential causes requiring consideration have been fully discussed, the focus of the discussion often naturally shifts towards the development of recommendations for change.

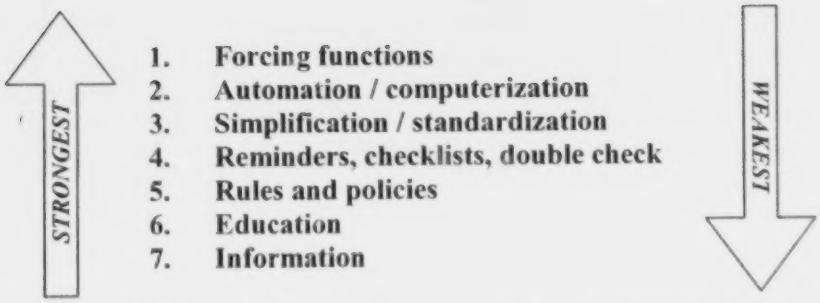
It is possible for an RCA to fail to yield the desired results. **"Without the strong support of upper management, root cause analyses may be performed in a perfunctory manner…It must be accepted throughout the organization that the results of any given root cause analysis will be for improving situations, not for assigning blame"** (Berry and Krizek, 2000).

It is important to separate discipline from quality review. If staff involved in the critical incident believe that information provided to facilitators will be used in a disciplinary forum, they are unlikely to be forthcoming with details of the incident. Marx (2001) proposed the idea of creating a "**just culture**" within health care organizations.

> "To promote a culture in which we learn from our mistakes, organizations must re-evaluate just how their disciplinary system fits into the equation. Disciplining employees in response to honest mistakes does little to improve overall system safety." *Marx, 2001*

7.4 Establishing Recommendations

Establishing recommendations for system change is the final component of the review. When recommending change, there is a distinct order to follow (see below) ranging from most effective to the least effective. The team should be apprised of this range, and encouraged to recommend the most effective solution that is reasonable and/or possible.



Recommendations should be included in the summary report along with the contributing root causes. It is essential that appropriate senior administrative staff or physicians be charged with the responsibility for leading development and implementation of the recommendations.

When the review team is satisfied that all relevant root causes have been identified and all plausible recommendations have been itemized, the facilitator can close the meeting. Since this process will continue to evolve within your organization, it is recommended that participants fill out an evaluation to promote continuous learning and improvement of the process.

7.5 *Implementing Recommendations*

The success of the RCA process depends upon the **actions taken** by the organization in response to the recommendations. All reviews should be tracked and a designated individual (Quality Improvement Coordinator or similar) within the organization should maintain responsibility for follow-up of all RCA recommendations. The Board of Directors and senior staff should be provided with **frequent updates** on the status of review recommendations.

As with any quality improvement initiative, a method of **measuring the effectiveness of change** following the implementation of the recommendations needs to be applied so that the intended improvements occur. If surveillance indicates that the changes did not have the intended affect, it will become necessary to revisit the issue to identify alternative solutions.

Following the review, a **summary report** will be prepared by the facilitator and distributed to a limited group of individuals with responsibility for the incident or implementation of the recommendations (see Appendix L for an example). This report should include the facts surrounding the incident, potential contributing factors or root causes, as well as the recommendations made and the person(s) responsible for development and implementation.

The distribution list for the summary report will typically include the CEO and appropriate administrative and medical management staff. The document should be clearly marked as **privileged and confidential**. Prior to circulation, other RCA participants may be provided with the opportunity to review the report.

Section 8. Conclusion

> *"In general, healthcare organizations have been late to adopt new organizational practices such as total quality and root cause analysis. This reluctance stems, in part, from a culture of individual responsibility tied to heavy investment in professional expertise and high variability among patients, in-group secrecy in response to a punitive legal environment, and organizational structures that reinforce boundaries between groups."*
>
> Carroll et al., 2002

A positive sign that more thought and emphasis is being placed on a more forward-thinking approach is the development of a new school of engineering thought called '**human factors engineering**.' Human factors engineering provides a framework for both developing efficient and constructive thinking in a health care setting, and includes methods and tools designed to assist teams in conducting all types of patient safety analyses, including RCA (Gosbee, 2002).

By employing RCA following critical incidents, we can meet the Institute of Medicine's challenge (2001) to redesign health care organizations by:

1. Redesigning care processes
2. Making effective use of information technologies
3. Managing clinical knowledge and skills
4. Developing effective teams
5. Coordinating care across patient conditions, services, and settings over time
6. Incorporating performance and outcome measurements for improvement and accountability

Using a "**just culture**" approach to target the underlying causes and providing feedback to the participants on the effectiveness of change are key to obtaining acceptance by health care providers. When used appropriately and applied effectively, RCA is a substantial tool with a potential to improve the safety of the health care system for current and future patients. By conducting root cause analysis, formulating solutions, testing and implementing change, and measuring effectiveness we can begin to build a **culture of safety** in health care.

The document is in draft version and feedback regarding its content is encouraged. Please direct correspondence to:

Ms. Paula Beard
Provincial Quality of Care Coordinator
Saskatchewan Health
phone: (306) 787 6992
fax: (306) 787 6113
email: pbeard@health.gov.sk.ca

Ms. Jennifer White
Provincial Quality of Care Coordinator
Saskatchewan Health
phone: (306) 787 0935
fax: (306) 787 6113
email: jwhite@health.gov.sk.ca

Dr. Ty Josdal
Medical Consultant
Saskatchewan Health
phone: (306) 787 5062
fax: (306) 787 6113
email: tjosdal@health.gov.sk.ca

Section 9. References

Bagian JP, Lee C, Gosbee J, DeRosier J, Stalhandske E, et al. Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about. *Joint Commission Journal on Quality Improvement* 27(10): 522-532, 2001.

Baker GR, Norton PG, Flintoft V, Blais R, Brown A, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal* 170(11): 1678-1686, 2004.

Berry K, Krizek B. Root cause analysis in response to a "near miss". *Journal for Healthcare Quality* 22(2): 16-18.

Berwick, Donald. Taking action: leading the reduction of error. Presented at the *Examining Errors in HealthCare Conference*, Rancho Mirage, CA: October 13-15, 1996.

Carroll JS, Rudolph JW, Hatakenaka S. Lessons learned from non-medical industries: Root cause analysis as culture change at a chemical plant. *Quality and Safety in Health Care* 11(3): 266-269, 2002.

Croskerry P. Cognitive forcing strategies in clinical decision making. *Annals of Emergency Medicine* 41(1): 110-122, 2003.

Davies JM, Hébert P, Hoffman C. The Patient Safety Dictionary. *Royal College of Physicians and Surgeons of Canada*, October 2003. Available online at http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf

Gosbee J. Human factors engineering and patient safety. *Quality and Safety in Health Care* 11(4): 352-354, 2002.

Government of Saskatchewan. Draft *Regional Health Services Act Regulations.*

Government of Saskatchewan. *Regional Health Services Act Bill 61, Section 58-Accountability*, 2002.

Hume M. Changing hospital culture and systems reduces drug errors and adverse events. *Quality Letter for Healthcare Leaders* 11(3): 2-9, 1999.

Institute of Medicine. To Err is Human: Building a Safer Health System, 1999.

Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century, 2001.

Joint Commission on the Accreditation of Healthcare Organizations. *Sentinel Event Forms and Tools* (JACHO) Retrieved from website www.jcaho.org February, 2004.

Marx D. Patient safety and the 'just culture': a primer for health care executives. *Columbia University*, 2001.

Mutter, M. One hospital's journey toward reducing medication errors. *Joint Commission Journal on Quality and Safety* 29(6): 279-288, 2003.

National Quality Forum. Serious Reportable Events in Healthcare: A Consensus Report. 2002.

Reason, J.T., "Human Error: Models in Management". *British Medical Journal*. 320: 768-770, 2000.

Rex JH, Turnbull JE, Allen SJ, Vande Voorde K, Luther K. Systematic root cause analysis of adverse drug events in a tertiary referral hospital. *Joint Commission Journal on Quality Improvement* 26(10): 563-575, 2000.

Spath, Patrice L., BA, ART, How to Find the Underlying Cause of Medical Accidents, *Forum on Quality Improvement in Health Care*, New Orleans, December 1999.

Veterans Affairs National Center for Patient Safety, Root Cause Analysis. Retrieved from website www.patientsafety.gov/tools February, 2004.

Wilder GL. Medication safety in home infusion care. *Journal of Infusion Nursing* 26(5): 311-318, 2003.

Wood DD, Johannsen L, Cook RI, Sarter N. Behind human error: cognitive systems, computers, and hindsight. Dayton, OH: *Crew Systems Ergonomic Information and Analysis Center,* Wright Patterson Air Force Base, 1994.

Index of Appendices

Appendix A _____ ***43***

Definitions from theCanadian Patient Safety Dictionary

Appendix B _____ ***47***

The Saskatchewan Evidence Act, Section 35.1

Appendix C _____ ***51***

The Regional Health Services Act, Section 58: The Critical Incident Regulations

Appendix D _____ ***59***

Saskatchewan Critical Incident Reporting Guideline, 2004

Appendix E _____ ***65***

Saskatchewan Health Draft Critical Incident Review Policy

Appendix F _____ ***71***

Regina Health District Team Case Review Policy

Appendix G _____ ***79***

Saskatchewan Health Issue Alert Template

Appendix H _____ ***83***

Saskatchewan Health Draft Disclosure Policy Guideline

Appendix I _____ ***89***

JCAHO Root Cause Analysis Matrix

Appendix J _____ ***93***

Ishikawa Diagram

Appendix K _____ ***97***

Care Mapping Process

Appendix L _____ ***101***

Critical Incident Review Summary Report

Appendix A

Definitions from the

Canadian Patient Safety Dictionary

(1 page)

Definitions from the Canadian Patient Safety Dictionary:

Recommended use of the term Cause:
That cause be identified as an antecedent set of actions, circumstances, or conditions that produce an event, effect, or phenomenon. A cause may be proximate (immediately precede) or remote (a factor in predisposing to) the event, effect, or phenomenon.

Recommended use of the term Root Cause Analysis:
That root cause analysis be defined as a systematic process of investigating a critical incident or an adverse outcome to determine the multiple, underlying contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and, if applicable, developing recommendations for improvements to decrease the likelihood of a similar incident in the future.

Recommended use of the term Adverse Event:
That adverse event be defined in one of three ways:

1. An unexpected and undesired incident directly associated with the care or services provided to the patient;
2. An incident that occurs during the process of providing health care and results in patient injury or death;
3. An adverse outcome for a patient, including an injury or complication.

Recommended use of the term Incident:
That incident be defined as including events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause, patients. Incident reporting systems are meant to capture any and all incidents that are worthy of reporting. They often fail to do so because practitioners do not know what they should report.

Recommended use of the term Critical Incident:
That critical incident be defined as an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence.

Recommended use of the term Risk Management:
That risk management in health care be defined as organizational activities designed to prevent patient injury or moderate the actual financial losses following an adverse outcome.

(Davies et al., 2003)

Appendix B

Saskatchewan Legislation:

The Saskatchewan Evidence Act, Section 35.1

(2 pages)

Evidence before quality assurance committees privileged:

35.1(1) In this section:

(a) "**board of governors**" means the:

(i) board of directors;

(ii) board of management; or

(iii) other head;

of a hospital that is legally authorized to operate the hospital;

(b) "**committee**" means a committee designated as a quality assurance committee by the board of governors or the bylaws of a hospital to examine and evaluate on an on-going basis the provision of care and services to patients in the hospital for the purpose of:

(i) educating persons who provide health care; or

(ii) improving the care, practice or services provided to patients by the hospital;

(c) "**hospital**" means:

(i) a hospital approved pursuant to subsection 3(1) of *The Hospital Standards Act*; or

(ii) a facility as defined in *The Mental Health Services Act*;

(d) "**legal proceeding**" means any civil proceeding or inquiry in which evidence is or may be given and includes a proceeding for the imposition of punishment by way of fine, penalty or imprisonment to enforce an Act or regulation made pursuant to an Act.

35.1 (2) Subject to subsection (4), a witness in any legal proceeding, whether a party to it or not:

(a) is not liable to be asked and is not permitted to answer any question or to make any statement with respect to any proceeding before a committee; and

(b) is not liable to be asked to produce and is not permitted to produce any report, statement, memorandum, recommendation, document, information, data or record that is:

(i) prepared exclusively for the use of or made by; or

(ii) used exclusively in the course of, or arising out of, any investigation, study or program carried on by;

a committee.

35.1 (3) Subject to subsection (4), no report, statement, memorandum, recommendation, document, information, data or record mentioned in clause 2(b) is admissible as evidence in any legal proceeding.

35.1 (4) The privileges in subsections (2) and (3) do not apply:

(a) with respect to medical and hospital records that are:

(i) prepared for the purpose of providing care and treatment to a patient in a hospital;

(ii) prepared as a result of an incident in a hospital, unless the facts relating to that incident are also fully recorded on a record described in subclause (i); or
(iii) required by law to be kept by the board of governors;

(b) to legal proceedings founded on:
(i) defamation;
(ii) inducing breach of contract; or
(iii) civil conspiracy;
based directly on any proceeding before a committee or any report, statement, memorandum, recommendation, document, information, data or record mentioned in clause (2)(b); or

(c) to disciplinary proceedings where the impugned conduct is a disclosure or submission to a committee.

35.1 (5) When made in good faith:
(a) the:
(i) disclosure of any information or document or anything in it; or
(ii) submission of any report, statement, memorandum, recommendation, document, information, data or record;
to a committee for the purpose of its being used in the course of any investigation, research, study or program carried on by the committee; and

(b) the disclosure of any information or document or anything in it that arises out of any investigation, research, study or program described in clause (a);

does not raise or create any liability on the part of the person making the disclosure or statement.

35.1 (6) No action lies against the members of a committee for any:
(a) disclosure of any information or document or anything in it made in good faith;

(b) submission of any report, statement, memorandum, recommendation, document, information, data or record made in good faith; or

(c) proceedings taken in good faith;
in the course of any investigation, research, study or program carried on by the committee.

1989-90, c.57, s.3.

Appendix C

Saskatchewan Legislation:

The Regional Health Services Act, Section 58

The Critical Incident Regulations

(6 pages)

Excerpt from the ***Regional Health Services Amendment Act, 2004***

Section 58 is repealed and the following substituted:

"Critical incidents

58 (1) In this section:

(a) **'critical incident'** means an incident that:

(i) arises as a result of the provision of a health service by a regional health authority or a health care organization; and

(ii) is listed or described as a critical incident in the *Saskatchewan Critical Incident Reporting Guideline, 2004* published by the department, as amended from time to time, or any subsequent edition of the *Saskatchewan Critical Incident Reporting Guideline*;

(b) **'legal proceeding'** means any civil proceeding or inquiry in which evidence is or may be given, and includes a proceeding for the imposition of punishment by way of fine, penalty or imprisonment to enforce an Act or regulation made pursuant to an Act, but does not include any prescribed proceeding;

(c) **'regional health authority'**, with respect to a critical incident that arises as a result of a health service provided by a health care organization, means the regional health authority of the health region in which the health service was provided.

(2) A regional health authority shall, in accordance with the regulations:

(a) give notice to the minister of the occurrence of any critical incident that arises as a result of a health service provided by the regional health authority; and

(b) investigate any critical incident mentioned in clause (a) and provide a written report to the minister with respect to that critical incident and investigation.

(3) A health care organization shall, in accordance with the regulations:

(a) give notice to the regional health authority of the occurrence of any critical incident that arises as a result of a health service provided by the health care organization; and

(b) investigate any critical incident mentioned in clause (a) and provide a written report to the regional health authority with respect to that critical incident and investigation.

(4) A regional health authority shall:

(a) give notice to the minister of any critical incident with respect to which the regional health authority receives notice from a health care organization; and

(b) provide the minister with a copy of any report with respect to a critical incident received by the regional health authority from a health care organization.

(5) Subject to subsection (7), a witness in a legal proceeding, whether a party to it or not:

(a) is not liable to be asked any question, is not permitted to answer any question and is not permitted to make any statement, with respect to an investigation of a critical incident; and

(b) is not liable to be asked to produce, and is not permitted to produce:

(i) any notice or report mentioned in this section; or

(ii) any information in a notice or report mentioned in this section or any documentation used to prepare a notice or report mentioned in this section.

(6) Subject to subsections (7) and (8), a notice or report mentioned in this section is not admissible as evidence in any legal proceeding.

(7) The privileges described in subsections (5) and (6) do not apply:

(a) to information in a notice or report that discloses the facts of a critical incident unless the facts relating to that incident are also fully recorded in a record other than the notice or report and are available to the patient; or

(b) to information that is prepared for the purpose of providing care or treatment to a patient, unless that information is also fully recorded in a record other than the notice or report and is available to the patient.

(8) Nothing in this section affects any privilege that may exist pursuant to section 35.1 of *The Saskatchewan Evidence Act* with respect to:

(a) a notice or report mentioned in this section;

(b) any information provided in a notice or report mentioned in this section; or

(c) any documentation used to prepare a notice or report mentioned in this section".

CHAPTER R-8.2 REG 3

The Regional Health Services Act

Section 64

Order in Council 536/2004, dated July 27, 2004

(Filed July 28, 2004)

Title

1 These regulations may be cited as *The Critical Incident Regulations*.

Interpretation

2 In these regulations:

(a) **"Act"** means *The Regional Health Services Act*;

(b) **"business day"** means any day other than Saturday, Sunday or a statutory holiday;

(c) **"guideline"** means the *Saskatchewan Critical Incident Reporting Guideline, 2004* published by the department.

Guideline adopted

3(1) The *Saskatchewan Critical Incident Reporting Guideline, 2004* is adopted, as amended from time to time, for the purposes of these regulations.

(2) The minister shall:

(a) cause the guideline to be made available to the public in any form or manner that the minister considers appropriate; and

(b) take any steps that the minister considers appropriate to bring the guideline, and the manner or form in which it is available, to the attention of the public.

Notice of critical incidents – facilities, services of RHA

4(1) A regional health authority shall, in accordance with sections 6 and 7, give notice to the minister of any critical incident that occurs:

(a) in a facility that the regional health authority operates; or

(b) in relation to a health service that the regional health authority provides or a program that the regional health authority operates.

(2) Notice pursuant to subsection (1) must be given within three business days, or as soon as possible thereafter, after the day on which:

(a) the critical incident occurs; or

(b) the regional health authority becomes aware of the critical incident.

Notice of critical incidents – facilities, services of HCO

5(1) A health care organization shall, in accordance with sections 6 and 7, give notice to the regional health authority of any critical incident that occurs:

(a) in a facility that the health care organization operates; or

(b) in relation to a health service that the health care organization provides or a program that the health care organization operates.

(2) Notice pursuant to subsection (1) must be given within three business days, or as soon as possible thereafter, after the day on which:

(a) the critical incident occurs; or

(b) the health care organization becomes aware of the critical incident.

(3) A regional health authority that receives notice of a critical incident pursuant to subsection (1) shall, in accordance with section 6, give notice of the critical incident to the minister within three business days after the day on which the regional health authority receives the notice from the health care organization.

Manner of giving notice

6 For the purposes of sections 4 and 5, notice may be given:

(a) orally by telephone or in person; or

(b) in writing, including transmission by facsimile or electronic mail.

Contents of notice

7 Subject to section 10, notice required by section 4 or 5 must include:

(a) a summary of the facts that led to the critical incident;

(b) a summary of the health status of the person to whom the critical incident relates:

(i) before the critical incident; and

(ii) after the critical incident;

(c) the actions that the regional health authority or health care organization, as the case may be, has taken or will be taking to investigate the critical incident; and

(d) a statement as to whether the critical incident has been reported to any organization that is not part of the regional health authority or health care organization, as the case may be, and the names of those organizations, if any.

Investigation and report of critical incidents – facilities, services of RHA

8(1) A regional health authority shall investigate any critical incident described in subsection 4(1) and prepare a written report with respect to each critical incident that it investigates.

(2) A written report required by subsection (1) must include:

(a) a description of the circumstances leading up to and culminating in the critical incident;

(b) a statement identifying any current practice, procedure or factor involved in the provision of the health service or the operation of the program that:

(i) contributed to the occurrence of the critical incident; and

(ii) if corrected or modified, may prevent the occurrence of a similar critical incident in the future;

(c) a description of the actions taken and the actions intended to be taken by the regional health authority as a result of the investigation; and

(d) any recommendations arising from the investigation.

(3) The regional health authority shall submit the written report to the minister immediately on completion of the report.

(4) If an investigation and a written report required by subsection (1) cannot be completed and the report submitted to the minister within 60 days after the day on which the regional health authority became aware of the critical incident, the regional health authority shall advise the minister of the delay, the reasons for the delay and the anticipated date of completion of the report, which is to be not later than 180 days after the day on which the regional health authority became aware of the critical incident.

Investigation and report of critical incidents – facilities, services of HCO

9(1) A health care organization shall investigate any critical incident described in subsection 5(1) and prepare a written report with respect to each critical incident that it investigates.

(2) A written report required by subsection (1) must include:

(a) a description of the circumstances leading up to and culminating in the critical incident;

(b) a statement identifying any current practice, procedure or factor involved in the provision of the health service or the operation of the program that:

(i) contributed to the occurrence of the critical incident; and

(ii) if corrected or modified, may prevent the occurrence of a similar critical incident in the future;

(c) a description of the actions taken and the actions intended to be taken by the health care organization as a result of the investigation; and

(d) any recommendations arising from the investigation.

(3) The health care organization shall submit the written report to the regional health authority immediately on completion of the report, and the regional health authority shall submit the report to the minister immediately on receipt of the report.

(4) If an investigation and a written report required by subsection (1) cannot be completed and the report submitted to the minister within 60 days after the day on which the health care organization became aware of the critical incident, the health care organization shall advise the regional health authority, and the regional health authority shall advise the minister, of the delay, the reasons for the delay and the anticipated date of completion of the report, which is to be not later than 180 days after the day on which the health care organization became aware of the critical incident.

Confidentiality

10 Notices required by sections 4 and 5 and reports required by sections 8 and 9 must not include:

(a) the name of any person to whom the critical incident relates;

(b) the name of any health care provider involved in providing health services to any person described in clause (a) or in operating a program to which the critical incident relates; or

(c) the name of any other individual who has knowledge of the critical incident.

Coming into force

11(1) Subject to subsection (2), these regulations come into force on the day on which section 58 of *The Regional Health Services Act*, as being enacted by *The Regional Health Services Amendment Act, 2004*, comes into force.

(2) If section 58 of *The Regional Health Services Act*, as being enacted by *The Regional Health Services Amendment Act, 2004*, comes into force before these regulations are filed with the Registrar of Regulations, these regulations come into force on the day on which they are filed with the Registrar of Regulations.

Appendix D

Saskatchewan Critical Incident Reporting Guideline, 2004

(4 pages)

Saskatchewan Critical Incident Reporting Guideline, 2004

By **"critical incident"** we mean a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority (RHA) or health care organization (HCO). (Additional definitions of terms can be found in Section VII of the Guideline.)

The following is a list of events that must be reported to Saskatchewan Health. The final item in each category allows for the possibility of adverse health events that fit the description given above, but were not anticipated when the list was created. Such events are also reportable.

I SURGICAL EVENTS (Surgery includes endoscopies and other invasive procedures)

a) Surgery performed on a wrong body part
(Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.)

b) Surgery performed on the wrong patient
(Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.)

c) The wrong surgical procedure performed on a patient
(Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.)

d) Retention of a foreign object in a patient after surgery or other procedure
(Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.)

e) Death during or immediately after surgery of an ASA classification I-II[1] patient
(Includes procedures where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately after surgery means within 24 hours of surgery or other invasive procedure, or, if surgery was not completed, within 24 hours of induction of anesthesia.)

f) Unintentional awareness during surgery with recall by the patient

g) An adverse health event leading to death or serious disability associated with any other surgical event while a patient is receiving a health care service provided by an RHA or HCO

II PRODUCT OR DEVICE EVENTS

a) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by an RHA or HCO
(Includes generally detectable contaminants such as infectious matter or foreign substances in drugs, devices, or biologics regardless of the source of contamination and/or product.)

---

[1] ASA Classification I - Normal healthy patient, II - A patient with mild systemic disease. Canadian Anesthesiologists' Society. *Appendix II: American Society of Anesthesiologists' Classification of Physical Status.* Retrieved May 2004 from website www.cas.ca.

b) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
(Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, ventilators, and mechanical devices used to lift, bathe, or shower patients.)

c) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for by an RHA or HCO
(Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.)

d) An adverse health event leading to death or serious disability associated with any other product or device while a patient is receiving a health care service provided by an RHA or HCO

III PATIENT PROTECTION EVENTS

a) An infant discharged to the wrong person

b) Patient death or serious disability associated with patient disappearance
(Excludes events involving competent adults.)

c) Patient suicide or attempted suicide resulting in serious disability while being cared for by an RHA or HCO
(Defined as events that result from patient actions after admission to a facility or program of the RHA or HCO. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to a hospital.)

d) An adverse health event leading to death or serious disability associated with any other patient protection event while a patient is receiving a health care service provided by an RHA or HCO

IV CARE MANAGEMENT EVENTS

a) Patient death or serious disability associated with a medication or fluid error including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration
(Excludes reasonable differences in clinical judgment on drug selection and dose.)

b) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products

c) Maternal death or serious disability while being cared for by an RHA
(Includes events that occur within 42 days post-delivery.)

d) Full-term fetal or neo-natal death or serious disability associated with labour or delivery while being cared for by an RHA
(Full-term fetus is >37 completed weeks gestation. Neonate refers to the first 28 days of life. Includes failure to screen for and prevent neonatal post-discharge dehydration or illness related to phenylketonuria.)

e) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for by an RHA or HCO

f) Neonatal death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinimia
(Hyperbilirubinimia is defined as bilirubin levels >30mg/dl. Neonate refers to the first 28 days of life.)

g) Stage 3 or 4 pressure ulcers acquired after admission to a facility of an RHA or HCO
(Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.)

h) Patient death or serious disability associated with a delay or failure to transfer a patient in keeping with the Saskatchewan Health Critical Care Patient Management and Transfer Process Policy

i) Error in diagnosis, where the treatment provided or not provided leads to patient death or serious disability

j) An adverse health event leading to death or serious disability associated with any other care management event while a patient is receiving a health care service provided by an RHA or HCO

V ENVIRONMENTAL EVENTS

a) Patient death or serious disability associated with electric shock while being cared for by an RHA or HCO

(Excludes events involving planned treatments such as electric countershock.)

b) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances

c) Patient death or serious disability associated with a burn incurred from any source while being cared for by an RHA or HCO

d) Patient death associated with a fall while being cared for by an RHA or HCO

e) Patient death or serious disability associated with the use or lack of restraints or bedrails while being cared for in a facility

f) Patient death or serious disability associated with the failure or de-activation of exit alarms or environmental monitoring devices

g) Patient death or serious disability incurred as a result of transport arranged or provided by an RHA or HCO

(Includes loss of control of a vehicle or aircraft, as well as actual or potential single vehicle accidents or multi-vehicle collisions, for example, transportation in a ground ambulance, air ambulance, medical taxi or chartered aircraft.)

h) Patient death or serious disability associated with a delay or failure to reach a patient for emergent or scheduled services provided by an RHA or HCO

(Includes delay due to extreme weather conditions, poor roads, communication breakdown. Includes, but is not limited to, EMS and homecare services.)

i) An adverse health event leading to death or serious disability associated with any other environmental event while a patient is receiving a health care service provided by an RHA or HCO

VI CRIMINAL EVENTS

a) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider

b) Abduction of a patient of any age

c) Sexual assault of a patient that occurs on grounds owned or controlled by an RHA or HCO

d) Patient death or serious disability from a physical assault that occurs on grounds owned or controlled by an RHA or HCO

e) Any sexual or physical assault of a patient perpetrated by an employee, member of the medical staff, or an individual under contract with an RHA or HCO
(Includes, but is not limited to, assaults perpetrated at a patient's home while receiving home care or mental health services.)

f) An adverse health event leading to death or serious disability associated with any other criminal event while a patient is receiving a health care service provided by an RHA or HCO

VII DEFINITIONS

"Adverse health event"
means an unintended injury or complication that is caused by health care management rather than by the patient's underlying disease process. Health care management includes the actions of individual staff members as well as broader systems and care processes. Health care management includes acts of omission (e.g. failure to diagnose, failure to treat) as well as acts of commission (e.g. incorrect diagnosis, incorrect treatment, poor performance).[2]

"Associated with"
means that it is reasonable to initially assume that the critical incident was due to the referenced course of care; further investigation and/or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship, but should not delay notification to Saskatchewan Health.

"Biologics"
means a drug that is prepared using a biological source material (derived from a microorganism, virus, animal, human, or plant) and using, for example, either conventional manufacturing methods, recombinant DNA technology, and/or other novel approaches. Some examples of biologics include vaccines, blood and its derivatives, certain hormones and enzymes, recombinant DNA products, gene therapies, and transgenics.[3]

"Disability"
means a physical or mental impairment that substantially limits one or more of the major life activities of an individual.

"Patient"
means a client, resident, or patient.

"Regional Health Authority" or **"Health Care Organization"**
includes any services or programs offered by the entities as defined in *The Regional Health Services Act.*

VIII REFERENCES

The *Saskatchewan Health Critical Incident Reporting Guideline, 2004* is adapted from:
The National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. National Forum for Health Care Quality Measurement and Reporting, 2002.[4]

---

[2] Definition adapted from Baker, G.R., Norton, P.G., et al. *The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada*. CMAJ 2004; 170:1678-1686.

[3] Definition adapted from Health Canada, Health Products and Food Branch, Therapeutic Products Directorate (www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_e.html).

[4] The National Quality Forum is a private, nonprofit, open membership organization created to develop and implement a U.S. strategy for healthcare quality measurement, and reporting.

Appendix E

Saskatchewan Health Draft

Critical Incident Review Policy

(4 pages)

Saskatchewan Health Policy & Procedure Manual	Policy No. Draft Cross Ref.
	Page 1 of 2
Section:	**Programs & Services (Risk Management)**
Subject:	**CRITICAL INCIDENT REVIEW POLICY**

INTENT:

To promote systematic identification of provincial critical incidents and facilitate timely, comprehensive, and effective review of their circumstances. The policy will form part of a system-wide approach to improving safety and quality in health care. The main reasons for proceeding with timely identification and review of critical incidents include:

- ✓ improved patient safety by directing comprehensive and effective review of incidents in order to determine potential contributing factors;
- ✓ promotion of multidisciplinary and system-wide involvement in identifying problems and recommending solutions;
- ✓ identification of systemic issues as opposed to focusing only on individual practitioner issues;
- ✓ development of a provincial network of support and assistance for internal and external reviews; and
- ✓ public reassurance (through a comprehensive and transparent process for managing incidents in health care).

POLICY: REPORTING OF CRITICAL INCIDENTS TO SASKATCHEWAN HEALTH

Definition of Critical Incident

"critical incident"

means a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority (RHA) or health care organization (HCO)

Saskatchewan Critical Incident Reporting Guideline, 2004

Critical Incidents signal the need for prompt investigation, understanding of root causes, and implementation of recommendations to improve the safety of the system as a whole.

Process

The RHA or HCO will ensure risk management processes are in place to identify and track incidents. Incidents are defined to include "events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause"[1] to a patient/client/resident. The incident may involve acts of commission (e.g. administration of the wrong drug) or omission (e.g. error in diagnosis, where the treatment provided or not provided leads to patient death or serious disability) and can be related to problems in practice, products, procedures and/or other aspects of the system.

[1] Davies J., Hébert P., Hoffman C., *The Canadian Patient Safety Dictionary*, The Royal College of Physicians and Surgeons of Canada, October 2003.

The identification of a critical incident shall trigger the actions outlined in this policy. Following a critical incident the immediate health, safety and well being of patients/clients/residents shall be given first priority. RHA and HCO policies and procedures will then be implemented in response to the identified critical incident and will include measures to meet the physical and psychosocial needs of applicable health care professionals. The breadth of the RHA or HCO response will vary depending on the individual circumstances surrounding the incident.

The Critical Incident Review Process (**Appendix A**) provides a coordinated framework for appropriate notifications and follow-up by key stakeholders. The process is outlined in detail within the appendices and includes the following actions:

1. Notifying appropriate parties based on RHA / HCO / provincial policy and applicable legislation (**see also Appendix B**).
2. Ensuring a comprehensive collection and review of the facts regarding the incident. Reviews may be either single- or multi-disciplinary in approach, depending on the circumstances.
3. Identifying and implementing any immediate changes that may prevent other similar circumstances.
4. Potentially expanding the review if the incident involves factors with system-wide implications.
5. Ensuring that any applicable recommendations generated by local or provincial review processes are implemented.

Notice of critical incidents may be given to the Provincial Quality of Care Coordinator(s) (787-6992 or 787-0935) or to one of your contacts in the following branches: Community Care, Primary Health Services, Population Health, and Regional Accountability. The provision of support to the region regarding the policy / process will primarily be provided by the Provincial Quality of Care Coordinators and/or the Saskatchewan Health Medical Consultant.

Steps for the Reporting of Critical Incidents to Saskatchewan Health

Notice of a critical incident provided within three business days; and

A report provided within sixty days as follows:

RHA → Minister

or

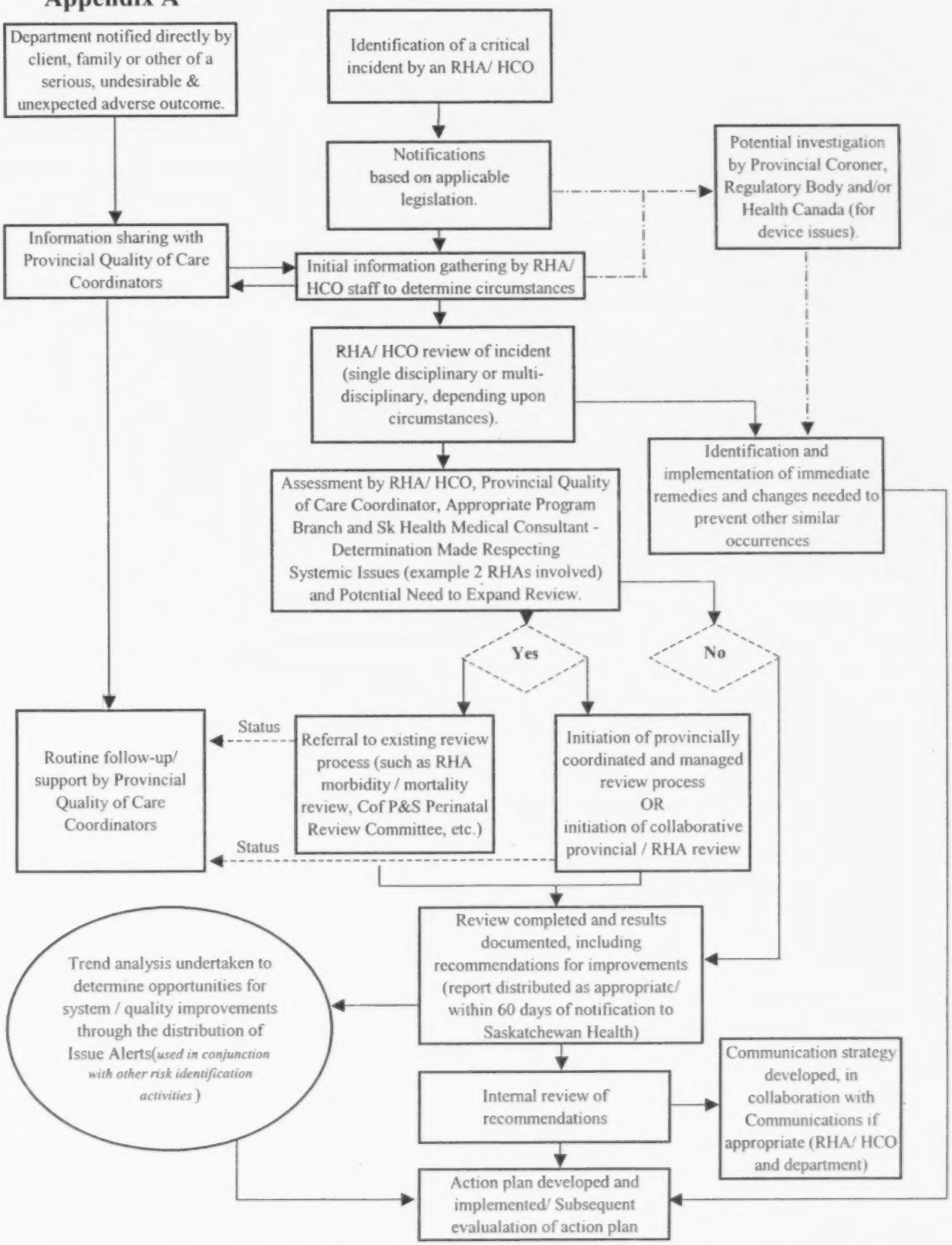
HCO → RHA → Minister

The report is to contain:

- the circumstances leading up to the incident;
- any current practice, procedure or factor involved in the provision of the health service that contributed to the occurrence of the critical incident and, if corrected, may prevent a similar critical incident in the future;
- actions taken, and actions intended to be taken, as a result of the investigation; and
- any recommendations for improvements to the system.

Approval Date:	Contact:

Appendix A


Department notified directly by client, family or other of a serious, undesirable & unexpected adverse outcome.
Identification of a critical incident by an RHA/ HCO
Notifications based on applicable legislation.
Potential investigation by Provincial Coroner, Regulatory Body and/or Health Canada (for device issues).
Information sharing with Provincial Quality of Care Coordinators
Initial information gathering by RHA/ HCO staff to determine circumstances
RHA/ HCO review of incident (single disciplinary or multi-disciplinary, depending upon circumstances).
Identification and implementation of immediate remedies and changes needed to prevent other similar occurrences
Assessment by RHA/ HCO, Provincial Quality of Care Coordinator, Appropriate Program Branch and Sk Health Medical Consultant - Determination Made Respecting Systemic Issues (example 2 RHAs involved) and Potential Need to Expand Review.
Yes
No
Routine follow-up/ support by Provincial Quality of Care Coordinators
Status
Referral to existing review process (such as RHA morbidity / mortality review, Cof P&S Perinatal Review Committee, etc.)
Initiation of provincially coordinated and managed review process OR initiation of collaborative provincial / RHA review
Status
Review completed and results documented, including recommendations for improvements (report distributed as appropriate/ within 60 days of notification to Saskatchewan Health)
Trend analysis undertaken to determine opportunities for system / quality improvements through the distribution of Issue Alerts(used in conjunction with other risk identification activities)
Internal review of recommendations
Communication strategy developed, in collaboration with Communications if appropriate (RHA/ HCO and department)
Action plan developed and implemented/ Subsequent evalualation of action plan

Appendix B

Notifications:

Prior to beginning the actual review process, a number of notifications regarding a reportable critical incident should be made. Each incident will involve unique aspects so the table should be adapted based on the circumstances.
Note – Not all of these notifications may apply in every instance.

Notification To:	Notification By:	Timeframe
Client / patient and / or family member [1] (and ensure that their needs are being met)	The attending health care professionals should consult organizational policies to ascertain who the notification will be provided by (i.e. physician and in-charge nurse, etc.) [2] Note – it is recommended that notification be made in the presence of two people for medico-legal reasons	As soon as possible after event occurrence
Attending Physician	Unit or program manager; in-charge nurse for the unit or service; and/or designated management personnel	As soon as possible after event occurrence
Internal notifications: CEO, Risk Management, Chief of Staff, QCC and other notification requirements as per organizational policy or protocols	Unit or program manager; and/or designated management personnel	As soon as possible after event occurrence
External notifications as per legislation and/or policy or protocols. Potential reporting includes Coroner, legal counsel / insurer and Health Canada – Therapeutic Products Directorate as applicable	Physician, in-charge nurse and/or designated management personnel	Immediate notification of Coroner and others as soon as possible after event occurrence
Saskatchewan Health	RHA CEO or designate	Within 3 business days as per regulations
RHA/ HCO communications / public affairs department	Quality Manager / Risk Management Office / QCC or designate	At RHA/ HCO discretion

[1] Disclosure to family member to be made only with the consent of the patient (or if the family member has the legal authority to represent and / or act on behalf of the patient).

[2] Please refer to organizational disclosure policies and/or the provincial guideline regarding the Disclosure of Harm to Patients.

Appendix F

Regina Health District Team Case Review Policy

(5 pages)

Regina Health District

TEAM
CASE REVIEW

A COORDINATED APPROACH TO MANAGING RISK

Approved by MQMC
September 2001

Approved by
Medical Advisory Committee
November 2001

Revised May 2002

TEAM CASE REVIEW

POLICY

A continuous process of self-evaluation and a desire to learn from the past are two key elements of effectively improving health care. Infrequently, serious, undesirable and unexpected outcomes occur that involve actual or potential loss of life, limb or function, or have a significant potential to adversely affect public perception of the quality of care.

Examples include:

- Any death, paralysis, coma or other major permanent loss of function associated with an adverse drug event;
- Wrong site surgery or wrong surgery performed;
- Equipment malfunction, unavailability or failure which could have or did jeopardize the patient;
- Lack of appropriate follow-up or monitoring by medical staff or employee which could have or did jeopardize the patient;
- All inpatient suicides;
- Where a patient is discharged from an inpatient bed or the emergency department and returns DOA, or dies elsewhere within 48 hours (excluding those patients diagnosed as palliative);
- A process or protocol failure that results in an actual or potential untoward outcome.

Those occurrences involving a patient, client or resident will be reported to Risk Management or Administrator on call, the most responsible physician and the Medical Department Head in a timely fashion. A confidential Occurrence Report [RHD 051A (6/98)] will be completed as per RHD Policy Number 1.4.2.04. **The event will be promptly investigated in a consistent manner that focuses on identifying the cause of the untoward/unexpected outcome and does not seek to find blame. This process will form an essential part of quality improvement activities for the Regina Health District.**

IMMEDIATE MANAGEMENT PRIORITIES

THE FIRST PRIORITY IS TO ENSURE THAT THE IMMEDIATE NEEDS OF THE PATIENT, CLIENT OR RESIDENT AND/OR THE FAMILY HAVE BEEN MET. THE PHYSICAN AND STAFF WILL DOCUMENT ON THE HEALTH RECORD THE SPECIFIC FACTS RELATING TO WHAT HAPPENED AND THEIR ACTIONS TO MEET THESE NEEDS. THE CORONER WILL BE CONTACTED AS APPLICABLE AND SAME WILL BE CHARTED ON THE HEALTH RECORD. ADDITIONAL ACTIONS WILL INCLUDE THOSE LISTED BELOW AND THAT WHICH IS REQUESTED BY RISK MANAGEMENT AND/OR ADMINSTRATOR ON CALL.

1) Notify
   - Manager/supervisor on call,
   - Most responsible physician if not already aware,
   - Risk Management or Administrator on call and;
   - Medical Department Head

2) Identify any medication or medication containers, supplies or equipment that may have contributed to the occurrence. Quarantine the object(s) after labeling "Do Not Use" (***immediately contact Clinical Engineering if biomedical equipment is involved).***

3) Complete a Confidential Occurrence Report [RHD 051A (6/98)] as per policy number 1.4.2.04.

4) Identify and address immediate needs of physicians and staff for Critical Incident Stress Management.

RISK MANAGEMENT OR ADMINISTRATOR ON CALL WILL DISCUSS THE CIRCUMSTANCES WITH THE APPLICABLE ADMINISTRATIVE DIRECTOR, MEDICAL DEPARTMENT HEAD AND CHAIR OF THE MEDICAL QUALITY MANGEMET COMMITTEE (MQMC). AT LEAST TWO OF THE THREE INDIVIDUALS CONSULTED MUST AGREE THAT A TEAM CASE REVIEW IS INDICATED FOR IT TO BE IMPLEMENTED. AD HOC TEAM CASE REVIEW MEMBERS WILL BE APPOINTED AND THE FACILITATOR WILL BE A MEMBER OF THE DEPARTMENT OF RISK MANAGEMENT. THE MEMBERSHIP OF THE REVIEW TEAM WILL INCLUDE:

1) the attending physician (if physician involvement in the event),

2) the manager(s), director(s) and/or department head of the department(s) involved,

3) selected staff who provided care and,

4) consultants at the discretion of any member of the team.

MANDATE OF THE TEAM CASE REVIEW MEMBERS:

- To meet, whenever possible within 30 days of notification of the occurrence.
- To review the health record, related documentation surrounding the occurrence and any relevant policies, procedures and or protocols.
- To interview individuals who may provide additional relevant facts or pertinent background information.
- To summarize their findings in a report to the Administrative Director, Medical Department Head, Chair of the MQMC, Chief of Staff and Chief Executive Officer within (to be determined) days of the occurrence. The report will concisely describe the circumstances that are believed to have led to the actual or potential adverse outcome and the recommended measures to prevent a similar occurrence (if in fact there are any).

Documentation is to be concise and focused on the facts of the topic. No copies are distributed of any reports prepared for this process. All documents are clearly marked, "PRIVILEGED AND CONFIDENTIAL – FOR MEDICAL QUALITY IMPROVEMENT PURPOSES." If e-mail is used, messages begin with the note, "Confidential – for Medical Quality Improvement Purposes" and should be discarded as soon as possible. Reporting outside of this internal review process should only be done on the advice or Risk Management and/or legal counsel for the district.

RECOMMENDATIONS

The recommendations may be discussed with relevant members of the administration and medical staff. They will determine the implications of the recommendations and the ability to implement same. Responsibility for implementing any changes, and monitoring their effectiveness will be assigned.

The discussion and opinions expressed at the review will remain privileged and confidential.

Appendix G

Saskatchewan Health Issue Alert Template

(1 page)

DATE

TO:

Issue Alert: **Recommendation for XXX**

Note: *Issue Alerts are released by Saskatchewan Health following the review of at least one critical incident of this type reported to the Department. A critical incident is described as a serious adverse health event including but not limited to, the actual or potential loss of life, limb or function related to a health care service provided by, or a program operated by, a regional health authority or health care organization.*

We anticipate your Region will want to give immediate attention to the recommendation(s) as outlined below.

Insert details of the incident/review here.

Saskatchewan Health would like to advise all regions of the following recommendation(s):

Recommendation:
Insert recommendation(s) here.

Thank you for your attention to this important matter.

Sincerely,

Dr. Ty Josdal
Medical Consultant
Saskatchewan Health

Lauren Donnelly
Executive Director
Acute & Emergency Services Branch

Appendix H

Saskatchewan Health Draft Disclosure Policy Guideline

(2 pages)

Saskatchewan Health	Cross Ref.	Critical Incident Reporting Policy **Draft #1**
	Contact	P. Beard/ J White, AESB
	Page	1 of 4
Section:	**Risk Management**	
Subject:	**DISCLOSURE OF HARM GUIDELINES**	

INTENT: To provide regional health authorities with guidelines related to the disclosure of adverse health events to patients and/or their families.

GUIDELINE: Disclosure of harm to patients.

Principles for the disclosure of harm to patients include legal and ethical considerations. Legally, disclosure is considered to be a continuation of the informed consent process. Ethically, when done with care, disclosure can bolster public confidence in the health care system. For reasons of autonomy, institutional responsibility, transparency, and because it is the "right thing to do", it is recommended that disclosure become embedded in the health care culture in Saskatchewan.

Arising out of consent, "patients must be told what *may* go wrong…it must surely follow that they also have a right to be told what has in fact gone wrong."

–Robertson 2002

Triggers for the disclosure of harm to patients:

Disclosure should be considered when harm has come to the patient as a result of the health care services provided. Disclosure may be considered in the presence of any of the following circumstances:

1. **The harm should have been anticipated and/or communicated during the process of obtaining informed consent;**
   Example: Prior to an abdominal surgery, a patient is told that there is a possibility the surgeon will knick the bowel during the procedure. This in fact happens, the bowel is repaired and the patient is given antibiotics to ward off possible infection. In this case, the surgeon should then disclose to the patient that knicking of the bowel did in occur.
2. **The harm was not anticipated therefore not communicated during the process of obtaining informed consent;**
   Example: A patient consented to have a left sided hernia repair performed under general anaesthetic. The surgeon repairs a right-sided hernia, then realizes his error and proceeds to perform the left sided hernia. In this case, the surgeon should disclose to the patient that an unanticipated event occurred during the surgery.
3. **The harm may have been caused by human or systemic error (this may not be immediately clear but should not delay disclosure).**
   Example: A Home Care patient is prescribed 10 units of insulin. The nurse arrives at the patient's home and accidentally administers 100 units of insulin and as a result the patient becomes hypoglycaemic. An ambulance is called; the patient is treated for their hypoglycaemia, and recovers. In this case, the attending physician and nursing manager for Home Care should disclose to the patient that he accidentally received ten times the usual dose of insulin, causing his hypoglycaemia.

When should disclosure occur?

Disclosure should occur as soon as possible subsequent to a triggering event. Ideally, disclosure would occur within 24-48 hours of the health care team first becoming aware of the event. However, there are some situations that require additional time for the discovery of accurate information to provide to patients, and the coordination of the disclosure process. This circumstance is frequently associated with disclosure involving multiple patients, equipment failure, or the potential for the spread of nosocomial infection.

If the need to disclose is not immediately obvious, consideration should be given to performing a scientific risk assessment to determine if harm is present. In the absence of harm, a near miss should prompt the organization to review issues associated with the event to ensure future patient safety, however disclosure is not required as no harm has been done.

Who should receive disclosure?

The patient or their substitute decision maker should receive disclosure, as is appropriate for the individual circumstances of each case.

Who should provide disclosure?

It should not be an individual's responsibility to provide disclosure; rather a team approach is best utilized for discussing harm with a patient and/or their substitute decision maker. The team may include the most responsible physician, medical manager, or Chief of Staff. Additionally, a representative for the region (i.e. manager/director for the clinical area(s) involved) may be present or any combination that may be appropriate to the circumstances. It may also be appropriate to include the organization's Risk Manager.

Lead for the disclosure discussions should rest with those who have the most knowledge of the event that led to the patient harm. Though not required, consideration should also be given to involving residents or students who were present for the event that caused harm, as the experience will create a basis for their future practice. Regardless of who attends the actual disclosure meeting, all health care professionals involved in the provision of services to the patient should be aware that disclosure has been provided.

Finally, the organization should consider what resources the patient might require during the disclosure meeting. The Client Representative or Quality of Care Coordinator can assist patients and their families by providing support both during and subsequent to the meeting. There may be additional treatments or procedures that the patient will need to undergo and/or follow-up meetings required to further discuss the event and the QCC will ensure continuity for the patient. Depending on the situation, it may also be beneficial to include a representative(s) social worker, grief counsellor, chaplain, or similar.

How should disclosure be provided?

Disclosure should be provided in a private, quiet setting. It is further recommended that those involved in the disclosure meeting will invoke other processes as necessary to ensure that the appropriate information is provided to the patient. This may include the need to access, **prior to the meeting**, the services of an ethics consult, social worker or legal counsel.

Those responsible for the disclosure discussion should establish the tone of the meeting by providing a clear understanding for what will happen during the disclosure. **Factual information should be provided professionally, compassionately, truthfully, and in the absence of blaming statements**.

What should be disclosed and how should it be documented?

Discussions should focus on factual information and emphasis should be placed on discussing what is currently known about the event that caused the harm. **Blame should not be assigned. Opinions should not be discussed. Speculation of cause, if not yet known, should not occur during the meeting.** Disclosure should not be delayed because all facts are not known, but the patient should be made aware that this is the case, and a follow-up discussion should be planned to disclose any new facts that are discovered.

The process the organization plans to use to review the circumstances of the event should be provided to the patient. The discussions should include clarification about what information cannot be provided to the patient by statute (i.e. opinions generated during quality assurance discussions will not be disclosed as per Section 35.1 of the *Evidence Act* and Section 58 of the *Regional Health Services Act*).

It may prove advantageous to have all documentation relevant to the event and/or harm incurred available during the meeting. In addition to having these documents available during the meeting, patients should be provided with information about how to access their health information and consideration should be given to waiving fees for obtaining copies of patient charts.

A brief and factual entry should be made in the health record reflecting the nature of the disclosure discussion with the patient or their substitute decision maker. The entry should include the date, time, any facts provided and who was present during the discussion. It may also be appropriate to keep a more detailed record of events with the occurrence or incident report and any other relevant documents in an administrative file secured by risk management personnel.

Multi-Patient Disclosure:

It may be appropriate to vary how disclosure occurs for events that involve more than one patient. Initial contact may include a registered letter, telephone call, or an invitation to an in-person meeting. Regardless of the way in which initial contact is made, an opportunity for an in-person private meeting should be provided to every patient involved. Group meetings set up by the organization are not encouraged for reasons of confidentiality of patient information and protection of the privacy of those involved.

Every attempt should be made to inform all patients involved at approximately the same time and, where possible, in advance of any media attention to the issue.

Multi- Jurisdictional Disclosure:

There may be disclosures that extend beyond jurisdictional borders as follows:

- A patient receives care and harm occurs as a result of the care in the originating jurisdiction but is not disclosed and/or known prior to the transfer of the patient to another jurisdiction.

or

- A process or event may be common to multiple jurisdictions where the opportunity now exists for variation in the decision to disclose.

In either of the above circumstances, effective communication and cooperation among both jurisdictions is key. Ideally, both jurisdictions should be a part of disclosure discussions. The lead will normally fall under the responsibility of the jurisdiction in which the event occurred. If issues become difficult to resolve, Saskatchewan Health may be approached to assist in facilitating the disclosure process.

Disclosure Policy:

It is the expectation of Saskatchewan Health that all regional health authorities prepare and implement the use of disclosure policies based on the principles and guidelines outlined in this document.

Definitions:

Adverse Event – An unexpected and undesired incident directly associated with the care or services provided to the patient.

Critical Incident - a serious adverse health event, including, but not limited to, the actual or potential loss of life, limb, or function related to the health care service provided or being provided by a regional health authority or health care organization by a person.

Error – The failure to complete a planned action as it was intended or when an incorrect plan is used in an attempt to achieve a given aim.

Harm - n 1: any physical damage to the body [syn: injury, hurt, trauma] 2: the occurrence of a change for the worse [syn: damage, impairment] 3: the act of damaging something or someone.

Substitute Decision Maker – A proxy or nearest relative as per *The Health Care Directives and Substitute Health Care Decision Makers Act, 1997.*

References:

Barron WM, Kuczewski MG. Unanticipated Harm to Patients: Deciding When to Disclose Outcomes. *Joint Commission Journal on Quality Improvement* 29(10): 551-555, October 2003

College of Physicians and Surgeons of Saskatchewan. Physician Disclosure of Adverse Events and Errors that Occur in the Course of Patient Care. Policy and Guideline document, April, 2002.

Davies JM, Hébert P, Hoffman C. The Patient Safety Dictionary. *Royal College of Physicians and Surgeons of Canada*, October 2003. Available online at http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf

Hebert PC, Levin AV, Robertson G. Bioethics for Clinicians: 23. Disclosure of Medical Error. *Canadian Medical Association Journal.* 164(4), December 2001.

Kraman S, Cranfill, L Hamm, G Woodard, T. Advocacy: The Lexington Veterans Affairs Medical Center. *Joint Commission Journal on Quality Improvement* 28(12): 646-650, December 2002.

Spencer, P. Developing a Hospital Policy Re: Disclosure of Adverse Medical Events. *Risk Management in Canadian Health Care* 4(6): 65-72, December 2002.

Webster's Revised Unabridged Dictionary, © 1996, 1998 MICRA, Inc. Accessed electronically at www.dictionary.com as of March, 2004.

Appendix I

JCAHO Root Cause Analysis Matrix

(1 page)

JCAHO Root Cause Analysis Matrix

NOTE: Provided for information purposes only.

Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events - June 2002

Detailed inquiry into these areas is expected when conducting a root cause analysis for the specified type of sentinel event. Inquiry into areas not checked (or listed) should be conducted as appropriate to the specific event under review.

	Suicide (24° care)	Med. Error	Proced. Cmplic.	Wrong site surg.	Treatment delay	Restraint death	Elopement death	Assault/ rape/ hom.	Transfusion death	Infant abduction
Behavioral assessment process [1]	X					X	X	X		
Physical assessment process [2]	X		X	X	X	X	X			
Patient identification process		X		X					X	
Patient observation procedures	X					X	X	X	X	
Care planning process	X		X			X	X			
Continuum of care	X				X	X				
Staffing levels	X	X	X	X	X	X	X	X	X	X
Orientation & training of staff	X	X	X	X	X	X	X	X	X	X
Competency assessment / credentialing	X	X	X		X	X	X	X	X	X
Supervision of staff [3]		X	X		x	X			X	
Communication with patient/family	X			X	X	X	X			X
Communication among staff members	X	X	X	X	X	X			X	X
Availability of information	X	X	X	X	X	X			X	
Adequacy of technological support		X	X							
Equipment maintenance / management		X	X			X				
Physical environment [4]	X	X	X				X	X	X	X
Security systems and processes	X						X	X		X
Control of medications: storage/access		X							X	
Labeling of medication		X							X	

1. Includes the process for assessing patient's risk to self (and to others, in cases of assault, rape, or homicide where a patient is the assailant).
2. Includes search for contraband.
3. Includes supervision of physicians-in-training.
4. Includes furnishings; hardware (e.g., bars, hooks, rods); lighting; distractions

Appendix J

Ishikawa Diagram

(1 page)

ISHIKAWA DIAGRAM

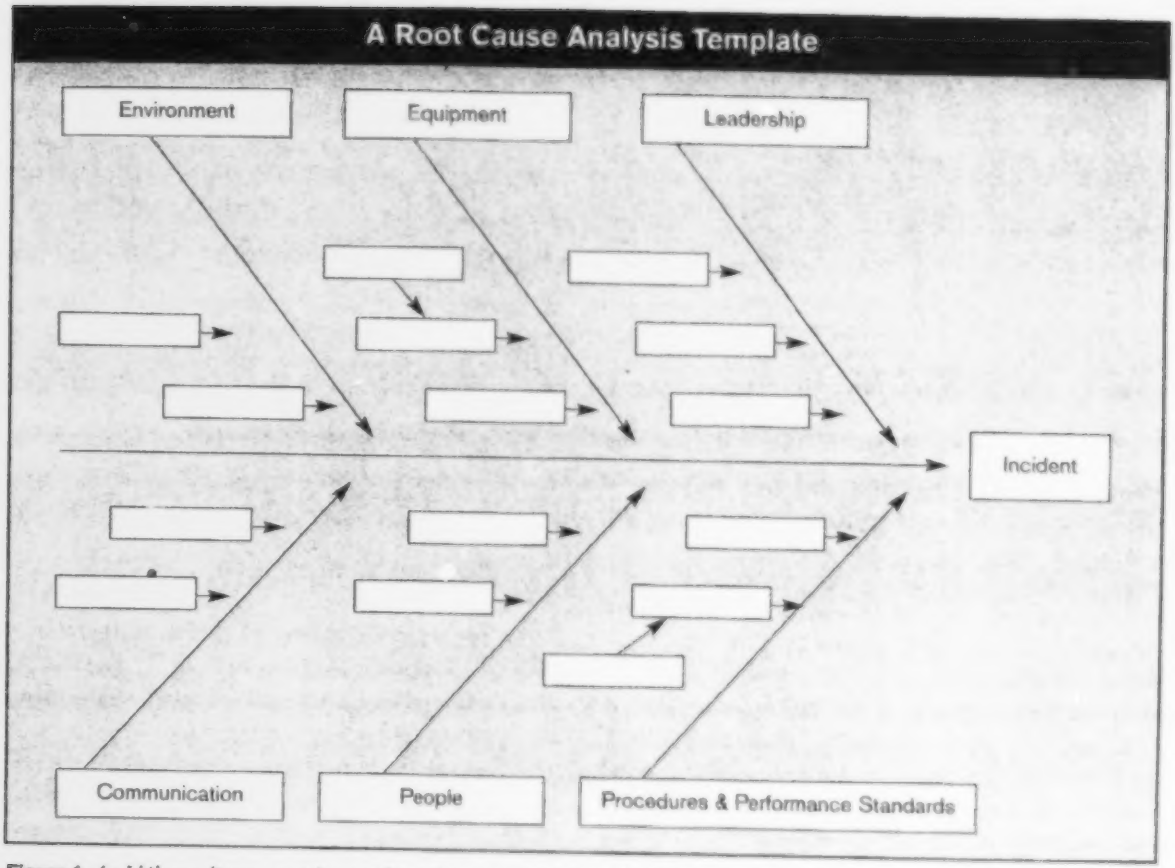


Figure 1. *An Ishikawa diagram template similar to this one was displayed during the root cause analysis. The exact labels for the categories are flexible and have been refined over time. Participants identified as many contributory factors as possible, and the session facilitator added these to the chart as they were identified and categorized by the participants.*

(from Rex et al., 2000)

Appendix K

Care Mapping Process

(1 page)

CARE MAPPING PROCESS

Medication Administration Process Flowchart with Quarterly Report Error Numbers

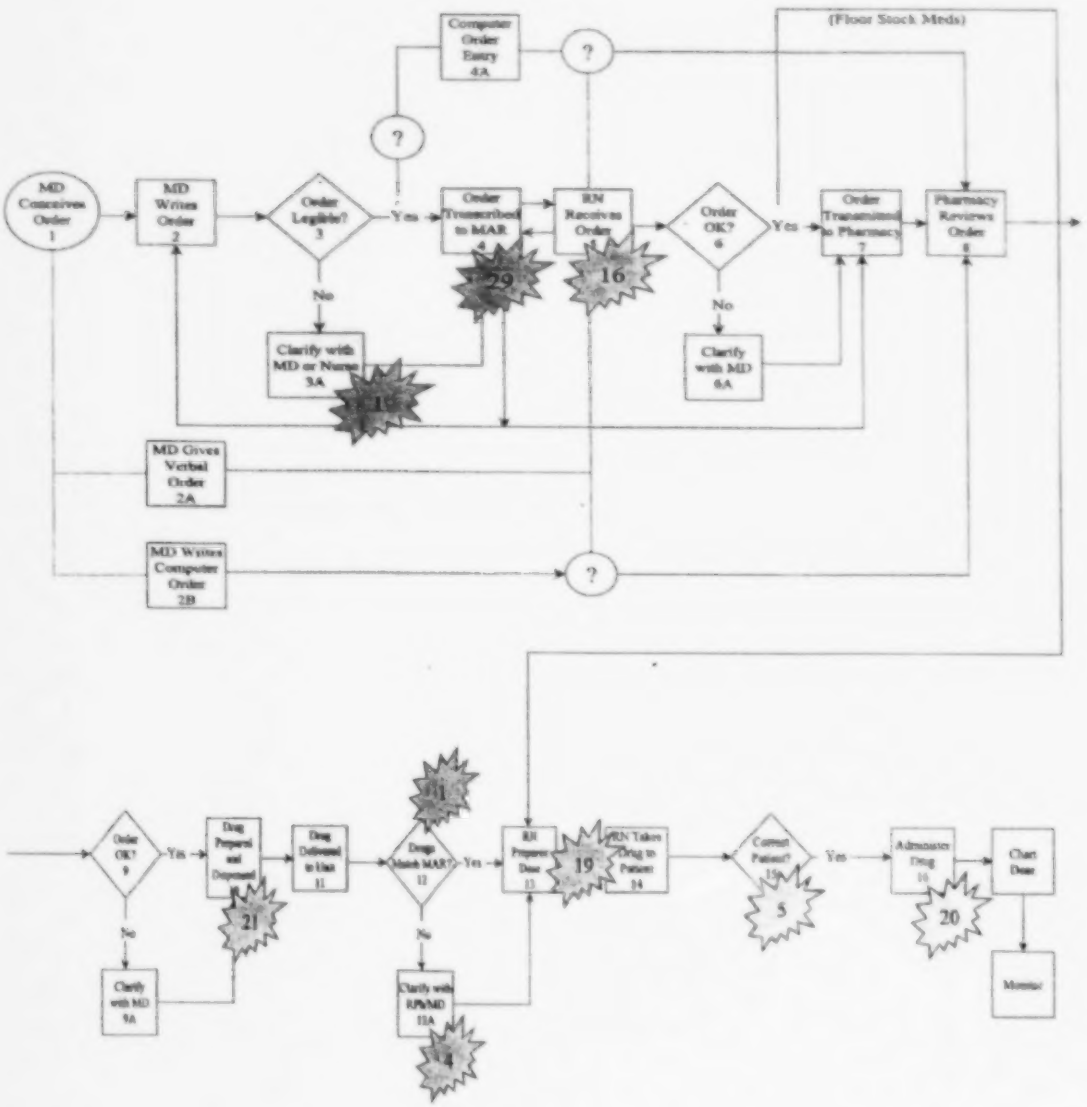


Figure 4. *Each error (indicated by a number in a starburst) is plotted on a flowchart of the medication use process—including ordering/transcribing, administering, and dispensing—under the step or point of impact—where it occurred. This information is collated on a quarterly basis to coincide with the quarterly meetings of the board of trustees. MD, physician; MAR, medication administration record; RN, registered nurse.*

(from Mutter, 2003)

CARE MAPPING PROCESS

Medication Administration Process Flowchart with Quarterly Report Error Numbers

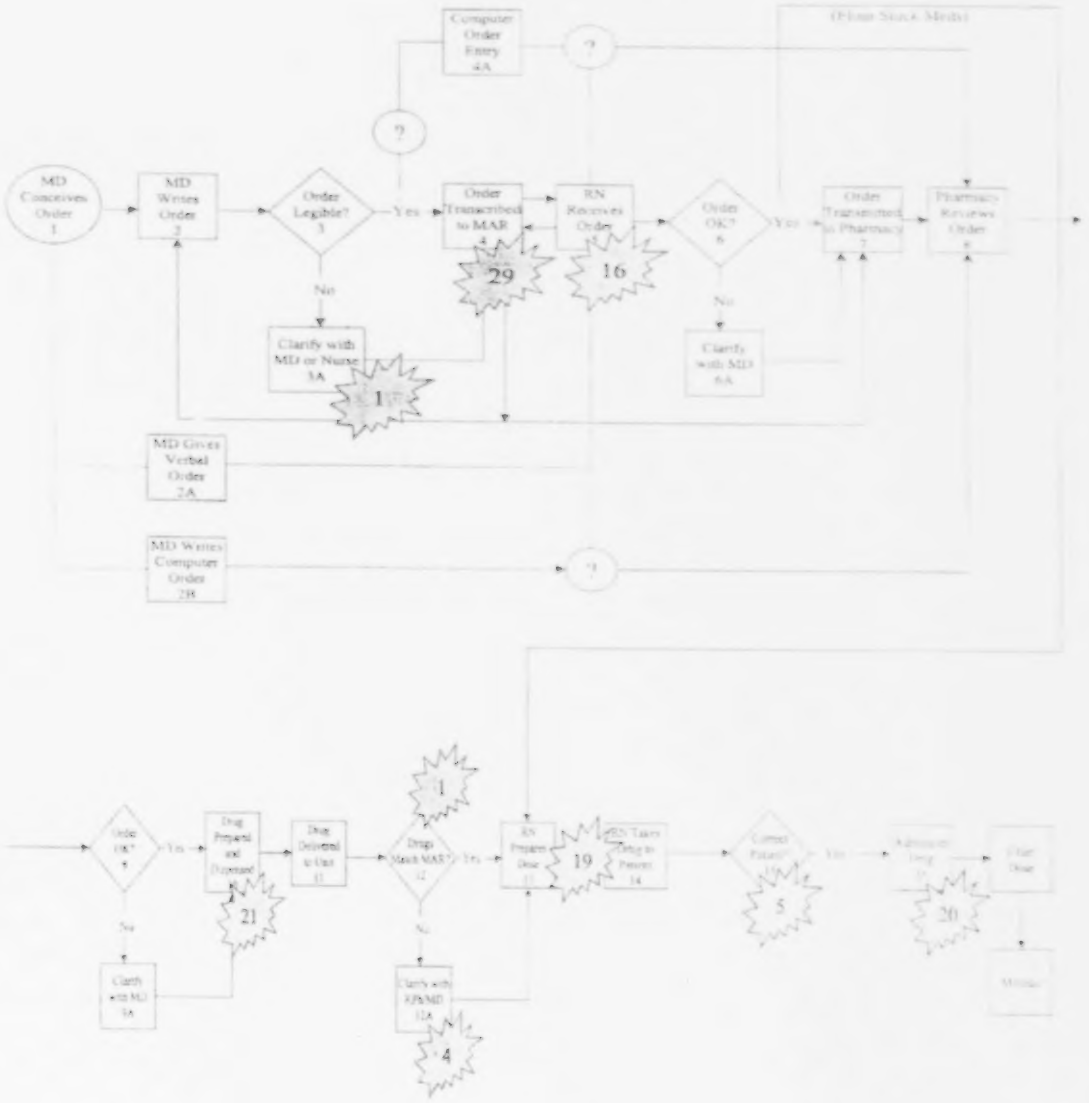


Figure 4. *Each error (indicated by a number in a starburst) is plotted on a flowchart of the medication use process—including ordering/transcribing, administering, and dispensing—under the step or point of control—where it occurred. This information is collated on a quarterly basis to coincide with the quarterly meetings of the board of trustees. MD, physician; MAR, medication administration record; RN, registered nurse.*

(from Mutter, 2003)

Appendix L

Critical Incident Review Summary Report

(5 pages)

Attending: Name and Designation

Facilitator: Name and Designation

I. Background Information

A critical incident was identified and a meeting was called by the Section Head, of _____ and the Director of _____ and the Director of _____. A facilitated review of the quality of care was conducted for Medical Quality Improvement. A report will be provided to the CEO, Chair of the District Medical Quality Management Committee, Chair of Medical Advisory Committeee, Vice President of _____ and Medical and Administrative Directors.

All materials are confidential and are protected by statutory privilege under Section 35.1 of the *Saskatchewan Evidence Act*.

The Facilitator will attempt to ensure equal participation by attendees and promote an open discussion of issues. A summary report will incorporate the factual sequence of events, applicable standards, policies, and procedures, potential contributing factors and any recommendations for quality improvement.

II. Introductory Comments

Participants introduced themselves and the facilitator thanked everyone for attending. She emphasized the importance of ensuring that opinions expressed at this review remain confidential in order to adhere to the philosophy and intent of Medical Quality Review.

Format for the session:

A. Identification and review of the relevant sequence of facts (a draft sequence had been prepared and was presented to participants).
B. Exchange of opinion and discussion to attempt to identify the factors that potentially contributed to the outcome.
C. Exchange of opinion and discussion to attempt to identify potential alternative actions.
D. If applicable, making recommendations for improving the care, practice or services provided to patients by the hospital and assigning responsibility for their development.

III. Sequence of Events - See enclosed table (Appendix 1)

IV. Applicable Standards, Policies, and Procedures - Summarized (Appendix 2)

V. Potential Contributing Factors (Appendix 3)

VI. Recommendations for Quality Improvement - See enclosed list (Appendix 4)

Appendix 1 -Summary of Sequence of Events-MRN:

Time	Event	Comments

Appendix 2
Applicable Standards, Policies & Procedures- Summarized

Appendix 3
Potential Contributing Factors

According to ***the Saskatchewan Evidence Act***, the following excerpt from *Section 35.1* titled *Evidence before quality assurance committees privileged* applies to Appendix 3 and 4 of the summary document.

(2) Subject to subsection (4), a witness in any legal proceeding, whether a party to it or not:
(a) is not liable to be asked and is not permitted to answer any question or to make any statement with respect to any proceeding before a committee; and
(b) is not liable to be asked to produce and is not permitted to produce any report, statement, memorandum, recommendation, document, information, data or record that is:
(i) prepared exclusively for the use of or made by; or
(ii) used exclusively in the course of, or arising out of, any investigation, study or program carried on by a committee.

The participants discussed potential contributing factors that may have led to the critical incident. Those factors were identified as follows:

1.

Appendix 4
Recommendations for Quality Improvement

In the spirit of quality improvement the following items have been identified as areas of development.

I. Policy and Procedure

Responsibility for Development:

II. Issues Referred to Medical Department

Responsibility for Development:

III. Resources

Responsibility for development:

Privileged & Confidential – For Medical Quality Review Purposes